

**COVID-19—2021**

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**HEARING**

BEFORE THE

COMMITTEE ON  
HOMELAND SECURITY AND  
GOVERNMENTAL AFFAIRS

AND THE

COMMITTEE ON RULES AND  
ADMINISTRATION

UNITED STATES SENATE

ONE HUNDRED SEVENTEENTH CONGRESS

FIRST SESSION

PREPAREDNESS FOR COVID-19: THE INITIAL PANDEMIC RESPONSE  
AND LESSONS LEARNED, APRIL 14, 2021 AND  
COVID-19 PART II: EVALUATING THE MEDICAL SUPPLY CHAIN AND  
PANDEMIC RESPONSE GAPS, MAY 19, 2021

Available via the World Wide Web: <http://www.govinfo.gov>

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Committee on Homeland Security and Governmental Affairs



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U.S. GOVERNMENT PUBLISHING OFFICE

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**PREPAREDNESS FOR COVID-19: THE INITIAL  
PANDEMIC RESPONSE AND LESSONS  
LEARNED**

WEDNESDAY, APRIL 14, 2021

U.S. SENATE,  
COMMITTEE ON HOMELAND SECURITY  
AND GOVERNMENTAL AFFAIRS,  
AND THE COMMITTEE ON RULES AND ADMINISTRATION,  
*Washington, DC.*

The Committee met, pursuant to other business, at 10 a.m., via Webex, Hon. Gary C. Peters, Chairman of the Committee, presiding.

Present: Senators Peters, Carper, Hassan, Sinema, Rosen, Padilla, Ossoff, Portman, Johnson, Paul, Lankford, Romney, Scott, and Hawley.

**OPENING STATEMENT OF CHAIRMAN PETERS<sup>1</sup>**

Chairman PETERS. This Committee will come to order.

First, I want to thank each of our witnesses for joining today's discussion, which will be the first in a series of hearings focusing on the Federal Government's preparation for, and response to, the coronavirus (COVID) pandemic.

We have to examine and confront our failures, identify and build on what went right, and propose reforms to ensure our Nation can combat this pandemic and be better prepared to prevent and respond to future pandemics, which we know will occur at some point, and other public health threats.

I appreciate Ranking Member Portman for joining me to conduct this bipartisan oversight of the Federal pandemic preparedness and response efforts. This approach is another clear example of how this Committee is stronger when we work together.

And no challenge requires a bipartisan approach more than tackling this once-in-a-lifetime pandemic. Since the first cases were diagnosed in the United States, more than 562,000 Americans have now lost their lives.

While Congress has provided critical relief over the course of this pandemic, millions of Americans lost their jobs, families continue struggling to make ends meet, and countless small businesses are being forced to close their doors permanently.

More than 4 million Americans are getting immunized every day and the number of deaths from coronavirus are declining, so there indeed is a light at the end of the tunnel.

<sup>1</sup>The prepared statement of Senator Peters appear in the Appendix on page 37.

But we are not out of the darkness yet, and I am concerned that cases continue to rise, particularly in my home State of Michigan right now.

Vaccines are certainly an important step to prevent the spread of COVID-19, but we still need to practice social distancing, wear masks, and follow the advice of public health experts to get the resurgence of this virus under control, especially as variants continue to spread all across the country.

Tragically, it did not have to be this way. The lives lost, the permanent changes to people's personal health, the economic devastation, and the long months of personal sacrifice and suffering were not inevitable.

Adherence to years of pandemic planning by prior administrations, decisive action, and clear leadership from the Trump administration could have helped mitigate this pandemic.

In fact, since the first whole-of-government pandemic response plan was published in 2005, the United States has had ample opportunity to prepare for this type of public health crisis.

Professionals across our government spent years working to improve our pandemic preparedness, from a pandemic response playbook drafted by the National Security Council (NSC) in 2016, to a 2019 Department of Health and Human Services (HHS) series of exercises called "Crimson Contagion" that simulated a highly contagious airborne influenza pandemic.

In 2019, I conducted an investigation and released a report that identified the serious national security risks posed by our overreliance on foreign manufacturers for critical drugs and medical supplies.

My report found the United States was unprepared to deliver vaccinations on the scale needed during a pandemic and made critical recommendations that could help onshore manufacturing for essential supplies.

Unfortunately, despite preemptive actions and warnings, the previous administration failed to take necessary steps that would have limited the impact of this coronavirus pandemic.

Instead of acting swiftly and decisively, the previous administration chose to sideline our Nation's foremost medical experts and failed to implement a comprehensive national strategy that left individual States to combat the virus all on their own.

In fact, we know President Trump was aware the virus was both deadly and contagious as early as February 2020. However, he continued to tell the American people it would "miraculously disappear" and initially even compared its effects to the common flu, when scientific evidence clearly showed that coronavirus was much more lethal.

At a time when the administration could have provided clear and consistent communication, supported scientific guidance on needed public health measures, and ramped up production of personal protective equipment (PPE) and other critical medical supplies through emergency contracts and fully invoking the Defense Production Act (DPA), among other critical actions, the previous administration sought to rather downplay the virus' severity to the public.

On top of those failures, there have been numerous reports of widespread political interference in Federal agencies' COVID-19 response, including reports that Health and Human Services political appointees reviewed and may have altered or delayed weekly scientific reports issued by the Centers for Disease Control and Prevention (CDC) about the pandemic.

The Trump administration's inaction and efforts to minimize the threat posed by COVID-19 contributed to the carnage our communities have seen over the past year.

Despite representing only four percent of the world's population, by January 2021, the United States accounted for nearly a quarter of the global COVID-19 cases.

There is no question that the Federal Government must learn from these missteps and urgently work to strengthen our pandemic response, to ensure that we can both combat the ongoing pandemic, and prevent the next crisis, whatever it may be, from reaching the magnitude we have seen with this one.

Today we will hear from former officials from key agencies in the Federal Government, all of whom are widely credited experts in their respective public health and emergency preparedness fields.

I look forward to a very frank and open discussion and clear and candid recommendations about what we must do to prevent past mistakes from moving forward. It is our duty to ensure that our Nation is better able to meet whatever the next crisis may be.

With that, I turn it over to Ranking Member Portman.

#### **OPENING STATEMENT OF SENATOR PORTMAN<sup>1</sup>**

Senator PORTMAN. Thank you, Mr. Chairman. I appreciate the fact that our oversight so far—and we have sent a lot of letters and done a lot of interviews—that that oversight has been not just bipartisan but nonpartisan, and that we have been able to set aside politics and focus on the facts and past events, but also on the road ahead of us and how we can learn from what happened during this unprecedented, tragic coronavirus situation.

First, though, I want to take a moment to acknowledge the extraordinary loss that our Nation has experienced. As of this morning, 559,741 Americans have died because of COVID-19. And like just about all Americans, I have lost friends, I have also lost former staff members, and we all join with the families in grieving those we have lost during this pandemic.

I also want to express my gratitude for the work and the sacrifice of those who have been on the front lines, particularly those health care professionals who have been out there on the front lines for all of us, 1,541 of whom died fighting this pandemic.

COVID-19 has been catastrophic; there is no mistake about that. It also presented an unprecedented challenge to, in many ways, an unprepared U.S. public health system. Why were we unprepared? That is one of the questions we will get into today.

Unlike emergencies more localized in nature, a pandemic is not a singular event. COVID-19 has stretched across our entire country, in fact, the entire globe, with no regard for borders or beliefs. The scope is unprecedented. It has stressed our supply and health

<sup>1</sup>The prepared statement of Senator Portman appears in the Appendix on page 40.

care systems—including our critical front-line personnel as we said—and it has stressed it often to a breaking point. We have seen the economic damage. Millions have lost their jobs as a result of pandemic restrictions.

We are here today to understand some important issues: the United States' preparedness and initial efforts leading into the COVID-19 pandemic; the initial Federal response; and to identify recommendations to improve Federal preparedness for future pandemics and other public health threats.

We owe it to those Americans who did die as a result of COVID-19, to their families and countless others who are struggling to make ends meet, to make this a serious, nonpartisan oversight effort. Looking at the steps the Federal Government took in the initial days of the pandemic, we have to learn from the experience for the future.

To that end, I think there are three issues that are important to address. First, CDC surveillance systems and the lack of testing limited our early response. We know that China irresponsibly downplayed the initial severity of COVID-19. In my view, there is no question about that. That presents questions about our ability to work with global partners, particularly China, to identify and combat pandemics in their nascent stages.

But how did we do in the United States at recognizing and communicating COVID-19 cases, symptoms, and deaths, once the pandemic reached our shores? The CDC can only communicate and address the issues it knows about and understands. In many instances, what we found out is that COVID-19 cases manifested in patient symptoms and were ultimately the cause of death, but that information was slow to reach the CDC. Why was that? Instead of seeing real-time data, the CDC was only seeing fragmented, historical data. Adding to surveillance challenges, diagnostic testing was slow to develop and then slow to scale up to the level required by the pandemic. Why was that? It is critical that we enable State and local public health officials to communicate effectively and directly to the CDC. We also must have the capability to scale up testing when needed. We know those things. We have to talk about how we can do that better. In a future pandemic, this could mean the difference between quick, life-saving decisions, or confusion, and the needless loss of life.

Second, who was in charge? Where was the accountability? This is something I look forward to asking some of our distinguished panel about today because they have a lot of experience in how these things are managed. The reoccurring narrative in interviews with former government officials, like the ones we have today, and public health professionals is that, in the initial stages of the pandemic, leadership roles were not well defined, and they still are not well defined, in my view, in some respects. This resulted in confusion at the Federal, State, and the local level and likely slowed our initial response considerably.

But we knew this was going to be an issue. In 2019, HHS ran an influenza pandemic tabletop exercise called "Crimson Contagion." That exercise identified the lack of defined leadership as a major challenge. The exercise found that insufficient and conflicting statutory authorities defining leadership roles hampered

the Federal Government's ability to effectively respond to a pandemic. Confusion about leadership was also an issue identified following the 2009–10 H1N1 pandemic. This should be a cautionary tale for us as we continue our review. It is not enough to identify issues; we have to be forward-thinking and actually implement solutions to the issues we discover.

Third, this unprecedented pandemic crippled the U.S. medical supply chain in the initial weeks of the pandemic. Why was that? It was due, in large part, to a longstanding overreliance on China for pharmaceuticals and other medical supplies, including PPE. Reports indicate that China, as early as December 2019, increased imports and decreased exports of medical supplies as their own needs increased, dramatically shrinking U.S. purchasing ability. Compounding this issue was the lack of an organic medical supply stockpile here in our country.

The Strategic National Stockpile (SNS), which we will talk a lot about today—the largest Federal repository of pharmaceuticals and critical medical supplies, available for rapid delivery to support the response to a public health emergency—was not adequate when those State and local supplies are depleted. It was, frankly, understocked. We need to talk about why and, again, how to prepare for the future. The SNS was never replenished, despite urgent requests, after the 2009 H1N1 pandemic, and, further, it was never meant for a nationwide response. This, too, was an issue we knew about. Past pandemic exercises and lessons learned from prior pandemics—such as H1N1—told us that the supply chain resiliency was an issue.

Now, let us consider this: A critical supply chain with a single point of failure. A Strategic National Stockpile that was never meant for a national response. I understand the supply chain has mostly recovered, and the stockpile is restocking, but we cannot allow these issues to impede a future pandemic response.

The tragic loss of life, the devastating impacts on the economy and American workers, and also the destabilizing effect on global stability and security has taken a toll on all of us and all nations. Given the extent of existing issues within the public health system I just discussed, it is little surprise that the initial pandemic response was chaotic and unorganized.

Again, Mr. Chairman, I appreciate the nonpartisan nature of this review so far, and I stress the importance of identifying a bipartisan way forward. We have to figure out how to come together, learn from these lessons, and be better prepared next time. I thank our witnesses for being here today. I look forward to hearing from them, and I look forward to hearing their thoughts on the way forward.

Thank you.

Chairman PETERS. Thank you, Ranking Member Portman, for your opening comments, and I, too, look forward to working closely with you and every Member of this Committee to find answers to the questions that we have and then put forward meaningful solutions and action plans. I look forward to that work.

It is the practice of the Homeland Security and Governmental Affairs Committee (HSGAC) to swear in witnesses, so if each of you who will be testifying—I know you are on video, but if you would

not mind standing and raising your right hand, we would appreciate it at this time. Do you swear that the testimony you will give before this Committee will be the truth, the whole truth, and nothing but the truth, so help you, God? If you would respond “I do,” please.

Dr. LURIE. I do.

Dr. GERBERDING. I do.

Mr. NIMMICH. I do.

Ms. ZIMMERMAN. I do.

Chairman PETERS. Thank you so much. You may be seated.

Our first witness today is Dr. Nicole Lurie, former Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services from 2009 until 2017. Dr. Lurie is currently the strategic advisor to the Chief Executive Officer (CEO) and response lead at the Coalition for Epidemic Preparedness Innovations, and during her 8-year term as Assistant Secretary for Preparedness and Response, she led the HHS response to a number of public health emergencies from infectious disease to natural and manmade disasters, and is responsible for many innovations in emergency preparedness and response.

Dr. Lurie, welcome to the Committee, and you are now recognized for your five-minute opening statement.

**TESTIMONY OF THE HONORABLE NICOLE LURIE, M.D.,<sup>1</sup>  
FORMER ASSISTANT SECRETARY FOR PREPAREDNESS AND  
RESPONSE (2009–17), U.S. DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

Dr. LURIE. Thank you, and good morning, Chairman Peters, Ranking Member Portman, and others. As you heard, I am Dr. Nicole Lurie. Let me just stress that today I represent only myself.

The role of government is to protect its people from harms and to build resilience to those that cannot be prevented, and that means preparing for the worst and scaling back when it is appropriate to do so. As we know, the U.S. Government has been preparing for a pandemic for decades, and as a country, we have developed, exercised, and refined plans, created robust authorities that have enabled nimble response systems and infrastructure, and as we know, these have been put to the test during many events which were successfully managed within existing authorities.

After the West Africa Ebola epidemic, the pandemic office at NSC was reconstituted and developed a comprehensive playbook. Countermeasure development was guided through a formal coordination process known as the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), and that process was significantly degraded. But even these actions cannot fully explain the failure to act when we were first alerted to a potential pandemic, and I want to peg that at the end of December 2019.

We lost a month of valuable time between then and when a public health emergency was declared. In part, I believe that a climate of fear and retribution had developed over the years leading up to the pandemic, and that this inhibited seasoned career employees in key agencies from stepping up and speaking out.

<sup>1</sup>The prepared statement of Dr. Lurie appears in the Appendix on page 43.

You have asked whether or not the authorities for a successful response were sufficient, and I believe the answer is generally yes. But all the authorities in the world cannot make up for the failure of leadership and its devastating outcomes.

Here are 10 things I think should have happened early on. As soon as hearing about the outbreak in China, the administration should have played out the likely scenarios, making a plan for each.

Communicating from the top in a clear, forthright, and consistent way about the severity of the threat and what to do about it.

Developing and executing a real-time research agenda.

Strengthening surveillance and testing. The failure of test development at CDC and the inability of State and local health departments to deal with testing and tracing is well-known, but the authorities to develop and scale testing were not leveraged, and public health and health care data remained largely unlinked, with signals of the staggering racial and ethnic inequalities going unaddressed for way too long.

Examining what was in the SNS. It was always clear there was not enough PPE, but emergency contracts to ramp up production in early January and to gain visibility into the supply chain should have been executed.

Recognizing and addressing the other health-related supply chain vulnerabilities predicted from the get-go.

Putting the health care system on alert so it could prepare the staff, supplies, policies, and for community-wide coordination.

Starting countermeasure development early, as soon as the threat was detected, to include diagnostics, therapeutics, and vaccines. The National Institute of Allergy and Infectious Disease (NIAID) jumpstarted work on an mRNA vaccine, but Biomedical Advanced Research and Development Authority (BARDA) was hamstrung in taking early action. While Operation Warp Speed (OWS) came together and did a phenomenal job with vaccine development, it could not make up for lost time, especially with regard to diagnostics and therapeutics.

As a point of reference, Coalition for Epidemic Preparedness Innovations (CEPI), where I work, was worried enough about an impending pandemic that its staff activated vaccine developers in early January, even before the sequence was posted. It could always take an off ramp, but not make up for lost time.

Coordinating across all levels of government and providing guidance for health care settings so people were not left to fend for themselves and compete with one another.

And mobilizing private sector partners.

I appreciate the opportunity to look forward, and here are a few things that I think we need to do.

First, I think we need to make it safer for career employees to do their jobs, including maintaining the integrity of our science agencies.

Second, reconceptualize the organization and role for public health. America needs a modern public health system, not just at CDC but across the country.

Third, maintain a standing emerging infectious disease fund at BARDA.

Four, reexamine the SNS, what it is for, ensure it can be activated for surge production on demand, and has responsibility for monitoring and addressing critical supply chains going forward.

Five, strengthen and clarify selected authorities at the Food and Drug Administration (FDA).

I will say, six, protect against cyber threats to our research, our manufacturing, our supply chains, and our public.

It is important to remember that preparedness requires continuous, proactive financial investment. It is all too easy to lose sight of the fact that preparedness is forever. We cannot afford to let our guard down. Almost 600,000 dead and still counting. We cannot make up for lost time or lost lives, but we can act on the hard lessons learned. Preparedness and response have always been bipartisan or nonpartisan, and I appreciate the spirit in which this hearing is being held.

Thank you.

Chairman PETERS. Thank you, Dr. Lurie, for your opening comments.

Our second witness is Dr. Julie Gerberding, a former Director of the Centers for Disease Control and Prevention at HHS from 2002 to 2009. Dr. Gerberding is currently the executive vice president and chief patient officer at Merck & Company. She also co-chairs the Center for Strategic and International Studies (CSIS) Commission on Strengthening America's Health Security. While at CDC, Dr. Gerberding led the agency through more than 40 emergency responses to public health crises. She has been recognized for her leadership in responses to anthrax, bioterrorism, and the September 11, 2001, attacks.

Welcome, Dr. Gerberding, and you may proceed now with your five-minute opening statement.

**TESTIMONY OF JULIE L. GERBERDING, M.D.,<sup>1</sup> FORMER DIRECTOR (2002–09), CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Dr. GERBERDING. Thank you so much. Chairman Peters, Ranking Member Portman, and all the Members of the Committee, it is an opportunity to appear today and do whatever I can do to contribute to improving upon the lessons that we have learned.

Unfortunately, we cannot expect this pandemic to be an isolated event, and what we can do now will help improve our overall preparedness and response for this crisis, but also for whatever is in store for us in the future.

We are in the middle of a war right now, and it is too soon to declare victory, but I am sure we will eventually prevail. We are dealing with on one side the virus, which continues to spread and cause severe disease in new populations and certainly new countries and new regions. We are dealing with variants, 15 so far that are of some degree of concern, and one of which, the B117 variant, which is now the dominant transmitted virus in the United States. But we are also dealing with vulnerability, a population of people that is increasingly vulnerable not just to the impacts of this virus

<sup>1</sup>The prepared statement of Dr. Gerberding appears in the Appendix on page 54.

but also the disruption in our social system, our care system, and the experiences that they have with the difficulties in sustaining care and treatment for their other underlying medical conditions.

On the good side, we have the vaccines, which I think have exceeded everyone's expectations. We have a lot more to learn about them, the safety, the long-term durability of their protection, and I will not be surprised if down the road we will need a 2.0 or a 3.0 vaccine armamentarium. But at the very least, this is an incredibly powerful tool, and we need to make sure that we can deploy it to all the people who need vaccination.

We also have vigilance, and I know this is a controversial topic, but we have seen around the world that vigilance really can contain this pandemic without vaccine. We need to ask our citizens to continue to contribute that part of the equation until such time that we really do have vaccine-induced immunoprotection.

In my written testimony, I try to summarize the critical requirements for success, the lessons that we have learned so far, and some of the action items that I think we could be taking right now that would strengthen our position. I will not review all of those, of course, but I do think that, in addition to the sort of interim lessons learned analysis, we need to strongly encourage a commission, a review of all of the complexities that this pandemic has created for us, something along the lines of the 9/11 Commission that Dr. Phil Zelikow chaired in the past. Some of us are actually involved in supporting the planning for such a commission. I think down the road that is going to really be helpful not just to this Committee but to our Nation as we harden our biosecurity front lines and really get serious about what we need to do to protect America. So let me just talk about four critical areas that I see as the most important right now.

First and foremost is still case detection, and while we have made incredible progress with the support of the private sector and getting all kinds of tests available, we are still missing cases, and that becomes extremely important in the construct of vaccine breakthroughs or recurrent infections in people who have been infected more than once, as we need to understand how the variants are playing into that and what really is the long-term outlook for protection. So we must continue that ability to test and look for the genomic variability.

In order to do that, we need to think about how to support the front line of that effort, and that takes more than emergency funding. We really have to transition to sustainable funding models that allow our public health system to invest and develop the workforce necessary to provide these services, but also a more proactive stance going forward, and that includes funding our immunization infrastructure, the data system modernization that you have already referred to, and the ability to use more modern techniques and tools in the digital space to improve the speed and accuracy of this overall case detection phenomenon.

We must also improve our care to sick people. I think we have made progress there, but we are not deploying the guidance, and the front-line workers are not necessarily using the tools that we have made available. As I said, we still need to slow transmission in communities, and we have new tools there, too. Merck, for exam-

ple, is hoping that we will be able to assess one of our antiviral medicines as a post-exposure prophylaxis tool, and there are others that might add to our ability to keep people out of the hospital and slow down transmission in our communities.

The last piece of this, of course, is countermeasure development. I have already said the biggest lesson learned is how important our biopharmaceutical and related ecosystem has been, surprising everyone with the speed, the collaboration, and the overall volume of countermeasures that have been coming forward. But we need to focus on the deployment of those countermeasures not just in the United States but globally, because, there is no wall tall enough to keep this virus out; and if it is being spread anywhere in the world, it presents a threat to us.

We also need to think ahead, and I hate to be a harbinger of negative information, but I think we are learning our lesson at a much faster pace now about how frequently these emergencies will occur. So we have to change our doctrine of response to being much more involved in predicting where spillovers will occur, preempting those spillovers, and expanding, at least an order of magnitude, our armamentarium of countermeasures through mechanisms like CEPI, National Institute of Health (NIH), and most certainly the private sector, which I believe we have learned is absolutely critical to both the development as well as the manufacturing of these countermeasures in real time going forward.

I will stop there and just thank you again for including me in this hearing.

[Pause.]

Senator PORTMAN. Mr. Chair, I think you are on mute.

Chairman PETERS. Oh, sorry about that. Thank you, Dr. Gerberding. You missed my “thank you.” Now that I am off mute, thank you for your testimony and for being here today.

Our third witness is Mr. Joseph Nimmich, former Deputy Administrator of the Federal Emergency Management Agency (FEMA) at the U.S. Department of Homeland Security (DHS) from 2014 to 2017. Mr. Nimmich is currently a partner at Potomac Ridge Consulting. He served in the United States Coast Guard (USCG) for over 33 years and retired in 2010 as a Rear Admiral. Mr. Nimmich has four decades of experience in disaster management and response and recovery operations.

Mr. Nimmich, it is great to have you here today to testify. You may proceed with your five-minute opening statement.

**TESTIMONY OF THE HONORABLE JOSEPH NIMMICH,<sup>1</sup> FORMER  
DEPUTY ADMINISTRATOR (2014–17), FEDERAL EMERGENCY  
MANAGEMENT AGENCY, U.S. DEPARTMENT OF HOMELAND  
SECURITY**

Mr. NIMMICH. Good morning, Chairman Peters, Ranking Member Portman, and members of the Committee. Thank you for this opportunity to appear before you. I am proud to have served as the Deputy Administrator at FEMA and in the U.S. Coast Guard. I hope my experiences provide insights useful to your program of learning lessons from the COVID–19 response and the future preparedness of our Nation.

The work of the Commission on the National Response Enterprise convened by Business Executives for National Security (BENS) has strongly influenced my thinking about the pandemic response. I was honored to serve as a Commissioner in this effort, along with a very august team of leaders from business, civil society, and government at all levels, including Senator Hassan and Senator Cassidy.

The whole-of-society approach to this challenge made the work of the Commission second to none, in my opinion, and resulted in 11 actionable recommendations for redesigning our response capabilities that I offer to the Committee to look at closely.

I want to start with some good news. The Commission found that the components of our integrated national response capability are largely in place, but COVID–19 response exposed critical execution challenges, particularly when a crisis impacts numerous States simultaneously.

I would like to focus on two of the areas of weakness identified today—that is, the exercising of our response plans and the surging of the human capital, the ability to respond to the crisis.

For exercising, the lack of planning really causes a performance shortfall. It is usually the fact that a plan is never as good as when it is first created. Time passes. New crises deflect decisionmakers' attention. People in positions change dissipating the trust between stakeholders, and the plan loses its effectiveness.

The U.S. had multiple plans for the response, and, Chairman, you have already indicated the exercise in 2019 called "Crimson Contagion." It encountered and predicted virtually every problem experienced less than several months later during the COVID–19 response. Why were we not more ready? The BENS Commission identified weaknesses in the national exercise program and contributed the performance challenges we saw in responding, including the low frequency of national-level exercises, the limited participant knowledge of our plans, the National Response Framework (NRF), and the crisis-specific action plans, the lack of clear understanding of authorities that are dictated in multiple authorizations and Homeland Security Presidential Directives (HSPDs), and the delegation of the responsibility for participating in those exercises from the decisionmakers to their subordinates. Only frequent and continual exercising keeps plans alive, enabling updating and improvements. When we think of Crimson Contagion, there was no

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<sup>1</sup>The prepared statement of Mr. Nimmich appears in the Appendix on page 60.

time to be able to improve the response from the time the exercise occurred because it occurred so late in the process.

Elevating the priority placed on exercising drives more effective coordination of the plans, and it allows the entire emergency response enterprise to be aware of the plans.

When we talk about surge, right now 80 percent of FEMA's workforce is deployed in support of national COVID-19 vaccination efforts as well as existing disasters. The problem is that these FEMA employees have day jobs. They run the National Flood Insurance Program (NFIP). They oversee the billions of dollars in grant programs. They hire the FEMA workforce. They provide the information technology (IT) that FEMA relies on. Continual deployment caused by escalating frequency and significance of disaster declarations has put unsustainable pressure on the FEMA personnel and the agency itself.

I am passionate about one of the Commission's recommendations to alleviate the pressure: the creation of a true civilian expertise reserve (CER) program for disasters. Modeled after the National Guard, these CERs could activate for service in both State and Federal crises and would provide emergency managers with a highly trained rapid response force of professionals, just as the National Guard does today. They would possess the skills and experience contemporary emergencies require: data analytics, cybersecurity, information technology, along with what we would expect, medical, engineering, and construction capabilities. They would have the same protections provided by USARA as the National Guard does.

The Guard's command and control structure could present a model for the CER management with State-based operations, a leadership hierarchy in each State, and a national leadership based in Washington, DC, to assume command of these forces when Federalized. As envisioned, the Civilian Expertise Reserve workforce gives the Nation a trained workforce to address disasters large and small, while delivering the essential capacity only when it is needed.

In closing, FEMA now has activated for nearly 400 days. That is five times more than the 70-day record of 2017. The dedication of every one of our Nation's first responders and FEMA employees is incomparable. They answer the call every single time America needs them. Congress needs to understand the pressures on FEMA, provide the necessary authorities and adequate resources for the agency's success. The Nation deserves it.

Thank you again for your time today, and I will be happy to answer any of the Committee's questions.

Chairman PETERS. Thank you, Mr. Nimmich. We appreciate you being here today and for your testimony.

Our final witness today is Ms. Elizabeth Zimmerman, former Associate Administrator for the Office of Response and Recovery (ORR) within FEMA from 2014 to 2017. Ms. Zimmerman is an internationally recognized emergency manager with over 35 years of experience, and during her tenure at FEMA, Ms. Zimmerman held dual titles of Associate Administrator and Director of Disaster Operations where she directed and coordinated programs and day-to-day operations within FEMA's Response, Recovery, Logistics,

and Field Operations Directorates, including during major disaster and emergency activations.

Welcome, Ms. Zimmerman. Good to have you here with us. You may proceed with your 5-minute opening Statement.

**TESTIMONY OF ELIZABETH A. ZIMMERMAN,<sup>1</sup> FORMER ASSOCIATE ADMINISTRATOR (2014–17), OFFICE OF RESPONSE AND RECOVERY OF THE FEDERAL EMERGENCY MANAGEMENT AGENCY, U.S. DEPARTMENT OF HOMELAND SECURITY**

Ms. ZIMMERMAN. Great. Good morning, Chairman Peters, Ranking Member Portman, and Members of the Committee. I thank you for the opportunity to speak with you today regarding the preparedness for COVID–19.

The COVID–19 pandemic is a maximum of maximum event that has stressed and challenged the United States' health, social, and economic systems. This was a national emergency, not just a public health emergency, and for the first time in our Nation's history, all 50 States, the District of Columbia, and the U.S. territories were under a State of emergency due to the consequences of COVID–19 being so severe, and they overwhelmed the State, local, tribal, and territorial (SLTT) governments.

COVID–19 differs from other State and regional emergencies in that every level of government was responding and focused on saving the lives of their residents, while attempting to prevent the collapse of their economy and medical systems. All levels of government and the private sector were competing for the same scarce resources such as medical personnel, PPE, and ventilators, while simultaneously attempting to prepare for the unknowns of the COVID–19 global pandemic.

Several issues arose in the early days of COVID–19 that in hindsight could have been handled more effectively and efficiently. Our Nation's emergency response and public health systems must learn from our recent experiences and mistakes by taking action now to update the plans, procedures, and better define the authorities to be ready for the next pandemic or any national emergency.

In my written Statement, I outline six areas that I believe require further exploration for lessons learned, including the issues and recommendations for these changes. The six areas included the plans, lead Federal agency, data management models and forecasting, commodities and logistics, the funding, and, last, the workforce. I am going to highlight a few of the issues and recommendations now.

The plans: The National Response Framework is the overarching foundational framework for how we as a country respond to and coordinate disasters. The NRF is used by all levels of government to develop their plans. At the onset of the pandemic, the NRF, the incident command and coordination system were not acknowledged as being used. COVID–19 was being managed by siloed health system operations, not coordinated across the whole of government or with the private sector. In mid-March 2020, when FEMA was named as the lead Federal agency and brought the response under the NRF and organized the National Response Coordination Center

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<sup>1</sup>The prepared statement of Ms. Zimmerman appears in the Appendix on page 65.

(NRCC), which is a system that everyone is trained, exercised, and accustomed to use.

Recommendations going forward is that the NRF should be used for all events and incidents as the foundation for response operations in the U.S. Any agency can lead the coordination under the NRF.

The second issue was designating a lead Federal agency. Many times during national crises, FEMA becomes the Federal Government's 911. COVID-19 was not the first time FEMA has been called upon to organize and/or lead events on behalf of another Federal agency that is outside of FEMA's Stafford Act authority. H1N1, Ebola, Zika, Flint water crisis, the surge and sheltering of unaccompanied minor children all fall within HHS' mission and responsibility.

FEMA was also involved in the U.S. Environmental Protection Agency (EPA) and U.S. Coast Guard's Deepwater Horizon response, the Department of Agriculture's (USDA) avian flu response, and the U.S. Department of Housing and Urban Development (HUD's) long-term recovery and housing missions. While FEMA successfully took on these responses, if FEMA is going to be the 911 for the Federal Government, they must be given authority, staffing, and resources to ensure successful outcomes.

Which leads to my third and final issue and recommendation that I will mention this morning. Typically, this time of year FEMA's workforce has down time amid responding to tornados, severe storms, and river flooding; however, this is not so in 2021. They have been working nonstop for over 15 months, with a record number of staff deployed, second only to the 2017 hurricane season, and they are expected to top that number of deployed staff by early May. They are stretched very thin, and we know hurricane season is right around the corner.

The recommendation is that if FEMA is going to be the go-to agency, their Reservist Program needs to be increased and professionalized, similar to the military reserve corps, as Joe Nimmich also mentioned earlier, where individuals can take a leave of absence from their jobs to serve their country and have the guarantee of returning to their job.

I thank you for the opportunity to participate in today's hearing. As a lifetime emergency manager, it is important for us as a Nation to make sure we include the whole community—government and nongovernment, private sector—in preparing for, mitigating against, responding to, and recovering from disasters. We need to be prepared now for the next pandemic. As COVID-19 demonstrated, it is not if but when it will happen. I look forward to our discussion this morning, and I thank you for this opportunity.

[The prepared Statement of Ms. Zimmerman follows:]

Chairman PETERS. Thank you, Ms. Zimmerman, for your testimony. You are absolutely right. The men and women of FEMA do not have any down time, and they certainly—we all appreciate their work. They are outstanding professionals, and we appreciate all that they do each and every day.

Last month, former White House coronavirus response coordinator Dr. Deborah Birx said, and I am going to quote Dr. Birx here: "There were about 100,000 deaths that came from the origi-

nal surge. All of the rest of them, in my mind, could have been mitigated or decreased substantially.”

That is certainly a pretty damning assessment in the wake of over half a million deaths in the United States and increasing cases in Michigan right now and in States across the country.

So my first question for you, Dr. Lurie—I am not going to ask you to put any kind of number on it, but, generally, would you agree with Dr. Birx’s assessment?

Dr. LURIE. Oh, absolutely I would agree, and I think there have been a number of, you know, modeling exercises that have suggested that 40-plus percent of the deaths were avoidable. I want to remind us that it is not only the deaths, but it is people who have suffered long-term health consequences from COVID; it is people who have suffered long-term mental health consequences from COVID; it is their families, and obviously the consequences of social and economic disruption.

I would also just say, going forward, there is still a lot of opportunity to avoid deaths, not only with vaccination but, as you and Dr. Gerberding point out, by taking seriously now the surge we are seeing in cases and having people take the appropriate public health measures. We are still all in this.

Chairman PETERS. Absolutely, we definitely are.

Dr. Gerberding, would you agree with Dr. Lurie and Dr. Birx, again, without giving any numbers but the general assessment of their Statements?

Dr. GERBERDING. Of course, I do not have the actual data or the modeling raw material, but I think it is common sense that if we had been able to identify cases and isolate them and their contacts sooner, we would have seen a much slower startup to this problem, and we would have bought a lot more time than we were left to deal with once we recognized how widespread it had already become. So that clearly is a major issue. The reasons for it are complex. I have tried to understand them from the outside looking in, but I think, as I mentioned in my written testimony, there are some things we can do now to harden ourselves against a future that brings that particular problem to bear, again, on the inability to respond initially.

I will also say that this is a shared responsibility. CDC certainly made its share of missteps at the beginning. We also needed some regulatory support for expanding access to tests when they became available, and then a faster mechanism to bring the private sector that can really scale testing into the situation. So the solution is broad but, nevertheless, it was a very early and unfortunate problem.

Chairman PETERS. No question about that, and I want to focus now with you, Dr. Gerberding, on the three week period in late February to early March 2020, at the very beginning of what we saw with this pandemic. The number of COVID-19 cases in the U.S. increased by more than 1,000-fold, according to the CDC—a critical period, clearly, at the beginning of this pandemic.

My question to you is: In your view, what factors led to that rapid rise in COVID-19 cases? And you have alluded to many of the different types of stuff, but if you could just focus in on that initial stage, which was just so critical, what steps could the Fed-

eral Government have taken to mitigate that spread right at the very outset during that three week period, late February to early March?

Dr. GERBERDING. Yes, I think it is tough. What we now know in retrospect is this is one of the most transmissible viruses we have ever had to deal with from a respiratory perspective. The fact that we had ongoing coronavirus transmission but essentially no flu transmission tells you what the differential is in terms of their probability of spread. So it was a really tough challenge, and it was made a lot tougher by not being able to get in there early and really not just look at people with a travel history or those that we suspected were at high risk, but to understand very early in the course of things that asymptomatic transmission was happening at a rate, again, somewhat unprecedented in disease transmission. And we also, I think, really would have been much more assertive about doing sampling studies, population-level sampling studies where we really look for the hot spots based on what we know about previous settings where viruses are easily transmitted by the respiratory route, and accelerated the science of the transmission coefficient so that we would be able to better predict where to go to look for cases even when testing was not widely available.

So in a sense, this was a failure of imagination, a failure to appreciate that this was not going to be like severe acute respiratory syndrome (SARS) or Middle East respiratory syndrome (MERS) where the efficiency of transmission from person to person was low. This was a disease that spread like wildfire, and we responded as if it were sort of business as usual.

Chairman PETERS. Dr. Lurie, I want to ask you a question related to those very initial stages as well where we saw this acceleration of the spread of the virus. In your testimony, you identify multiple missteps in that initial response, and you specifically highlight—and I want to quote what you specifically highlight. You say, “. . . all the authorities in the world cannot make up for the failure of leadership.”

My question to you is: What avoidable harm, in your view, flowed most directly from this failure of leadership as the initial pandemic response unfolded in January, February, and March of last year?

Dr. LURIE. I think the avoidable harm started with the ability of the virus to spread like wildfire because we did not acknowledge that it was going on and we did not take the steps to contain it, either the public health kinds of measures that Dr. Gerberding talked about, the steps to ramp up things like the production of masks and PPE to protect health care workers and to protect the supply chain and others, and everything that has unfolded from there.

If you think that the first 100,000 cases were maybe unavoidable, or less, certainly we could have changed the trajectory of this and saved countless lives.

So the failure to take all of the early actions, those that I mentioned and more, were really all avoidable and would have been much more avoidable had there been open and public acknowledgment of these risks. Even if we did not know how bad it was, it was our responsibility to prepare for the worst and to alert the public.

The other really avoidable harm has been the politicization of this, and so the public has gotten really confused about who to believe, what to believe, and obviously, people are still at odds with each other over a lot of aspects of this.

Chairman PETERS. All right. Thank you.

Ranking Member Portman, you are recognized for your questions.

Senator PORTMAN. Great. Thank you, Mr. Chairman. And thanks to all the witnesses.

I want to start with the surveillance issue. We talked a lot this morning already about CDC, but what happened? Why didn't CDC have the ability through the surveillance systems that we had in place to be able to detect this sooner? It seems to me they were relying on incomplete and outdated public health information, among other things, as I said in my opening. Some of you have talked today about the need for digital monitoring and that there were early warning signals that were not picked up.

Dr. Gerberding, you focused on that. What sort of surveillance indicators was the CDC relying on at the outset of the pandemic to inform the public health response?

Dr. GERBERDING. I think first and foremost was to take a look at what was going on globally. We had some information about the extent of spread in the Wuhan Province. We had examples of pretty well documented spread from travelers into work settings in other parts of the world. I think the clues were there that this was a very transmissible infection, unlike SARS was in 2003. So that was the first thing, is to lean into the threat that exists.

The second thing is testing and, you know, I think it was unlikely, even under the most rehearsed scenario, that we would have been able to immediately deploy a test for a brand-new pathogen to 300 million people on short order. But we certainly could have utilized the tests that were available elsewhere in the world that had proven to be useful, and we could have worked much faster to bring the scale of testing up to speed with better cooperation and earlier engagement of the academic sector as well as the private sector. So the first thing that needs to happen is case detection and then the isolation of the cases, the quarantine of their contacts.

Now, that is a problem in the United States because finding contacts is basically shoe leather right now. It means you have to go out and more or less door-to-door to track down the people who might have been exposed. And our workforce is way too thin to have been able to accomplish that once we had so many cases. It became almost impossible.

I think a third piece of this is to use our epidemiologic common sense and recognize that with a respiratory pathogen there are going to be certain congregate settings—confinement, high degrees of contact—where there is likely to be transmission, and to get into those settings first, do the testing and the epidemiologic assessment so we are ahead of the curve rather than waiting until cases were hospitalized and then find the hot spots in retrospect. So a lot of things are a combination of testing, workforce scarcity, and I think, again, just the inability up front to imagine how bad it was going to be.

Senator PORTMAN. I would like to dig a little deeper on the testing with you and Dr. Lurie and anybody else who wants to jump in. But backing up on surveillance for a moment, because it is not just about testing, as you indicate it is also about the World Health Organization (WHO) telling us what was going on, which they did not, China being more transparent, we know that. But what type of fixes do you think we need to make beyond additional funding, which I appreciate, and I appreciate the fact that you said the personnel are needed. You mentioned, for instance, using technology better in your testimony and digitizing some of this. Just quickly, if you could, what could we do under a surveillance system, in addition to testing, to make it more effective?

Dr. GERBERDING. One really important point that I think is implied in your question is that this is a global challenge, and if we had really actualized the promise of the global health security agenda, we would have had much better insight into where this disease started and how fast it was spreading internationally. We do need to come back to that global network of surveillance, not just a U.S. network. In the United States, I agree with you on the digital tools and the application of our technology in new and exciting ways, but at the end of the day, it boils down to case detection as the first step.

Senator PORTMAN. Yes, let us talk about testing for a second. Again, anybody is free to jump in here. I tell you, my frustration on testing was that CDC—and some of you have been involved in CDC over the years, and, there is plenty of blame to go around here. But CDC had lousy tests. In Ohio, we were given a bunch of CDC tests, and that was the only place to get tests, as we understood it. They did not work. There were defects in them. It prevented our labs from being able to validate the tests, rendering them basically useless.

I do not know if you know this, but in Ohio, the result of this was that some of the private sector jumped in, and particularly the Cleveland Clinic developed its own test, and I will give you some dates here. We got our botched tests from CDC on February 7th. We did not get a working test from CDC until March 5th, so virtually a month went by. And talk about a waste and an opportunity to save lives. And the Cleveland Clinic developed their own test and put it online on March 13th. That test I took, by the way, early on. But why were we so reliant on CDC? Shouldn't we have been encouraging the private sector to be involved all along? Again, Dr. Lurie, if you could jump in here, how did the legal and regulatory landscape at the time help or hinder institutions like the clinic, to use them as an example, but there were groups all over the country doing this, developing their own tests? Could you respond to that, Dr. Lurie?

Dr. LURIE. Yes, sure. What I would say is, when it was clear very early on that we were going to need an awful lot of tests, and tests were developed around the world. As Dr. Gerberding said, some of them worked quite well, and we could have used them. When CDC was struggling with its tests, or even before, BARDA should have exercised its authorities and gotten in early on to stimulate the development of diagnostic tests across the private sector and in the

academic sector so that you would have had a variety of tests earlier.

No one—there was no entity that took responsibility for pulling samples together to validate diagnostic tests, and so all the test developers really struggled. And so FDA gave an awful lot of them a pass and said, well, you are not going to need an Emergency Use Authorization (EUA); we are going to go ahead and assume a number of things. Then it turned out that we had diagnostic tests that did not perform well at all and had to come back off the market.

So the failure to get in early, ask the private sector to develop tests, agree to work with them, provide the sept that they would need for validation, and then be able to scale I think were really significant failures stemming from the failure to want to recognize that this was happening.

Senator PORTMAN. Thank you. We have to learn from that, clearly, and, it amazes me that we were so ill prepared in terms of our diagnostics.

My time is coming to an end. Admiral Nimmich, I had planned to ask you some questions about the BENS Commission. I appreciate the work on that. Senator Hassan was involved, who is on the panel today, and Senator Cassidy. But we really have appreciated that, and we are using some of your work. I guess the planning and the exercises, were not adequate in this case, and one question I want to leave with you as I end my time is: Is FEMA the right organization to head up something like this? There is a difference of opinion as to whether it should have been HHS or FEMA. And was FEMA the right entity? I will sort of leave that question out there hoping that somebody else follows up on it who has more time available.

Thank you, Mr. Chairman.

Chairman PETERS. Thank you, Ranking Member Portman.

Senator Hassan, you are recognized for your questions.

#### **OPENING STATEMENT OF SENATOR HASSAN**

Senator HASSAN. Thank you, Chairman Peters. And to Ranking Member Portman, thank you as well for the nonpartisan approach that you have taken to convening this hearing.

To our witnesses, thank you for being here today, but also thank you for your service.

I do want to start with a question to Mr. Nimmich, and I will ask you the question, and then if you want to fold into your answer a little bit about your thoughts to Senator Portman's question, that is fine, too.

It was really a pleasure, Mr. Nimmich, working with you on the BENS Commission on the National Response Enterprise. In your testimony, you discussed one of the topics addressed by the Commission, which is the importance of exercising emergency plans. A report from the 2019 Crimson Contagion exercise found that, with regard to the crisis in that exercise, there was "confusion between HHS, FEMA, and the Department of Homeland Security on which Federal agency would take lead in the crisis." Unfortunately, we witnessed this very same confusion between the role of HHS and FEMA during the COVID-19 pandemic, and this confusion cer-

tainly contributed to an overall lack of coordinated national response.

First, Mr. Nimmich, do you support updating the Stafford Act to clarify FEMA's response role to include pandemics?

Mr. NIMMICH. I think the two questions are highly related, and the question really comes, support and supporting. I use an awful lot of Department of Defense (DOD) concepts because response to whether it is a Department of Defense issue or a domestic issue, responding is pretty standard. I do not think it is—it is a requirement that we identify early on who is the lead agency and who is supporting them. You can add into the Stafford Act for pandemic, for cybersecurity, cyber events, and that would allow FEMA to be funded to do the work that is necessary. But it does not have to put FEMA in the leadership role. FEMA coordinates, and they take the rest of the whole of government and bring it to the event.

I do think that FEMA has a role to play in a pandemic. It has a role to play in almost any type of a national crisis. But it does not necessarily have to be in the lead, but it has to be defined early. The pandemic playbook that the NSC had in their hands had triggers of when certain things should happen, and those triggers rely on the data, whether it comes from CDC or someone else. You have to validate those. You have to exercise that and make sure each administration is comfortable that the data they are receiving, when the trigger is set, that they know who they are going to put in charge.

Senator HASSAN. Thank you. I want to follow up on that a little bit just in terms of the exercise issue as well, because regarding the 2019 exercise that identified this potential problem, how do we ensure that the Federal Government is actually implementing improvements on what is learned from these emergency exercises?

Mr. NIMMICH. I think that is a great question, and the challenge always is where do the resources and the policy changes being made in order to address the problems you found in the exercise. All too often we say that was a great exercise; we planned for what we can do and not necessarily what will be done. I ran the Spill of National Significance (SONS) exercise in January and February 2010. We did a great job. We identified certain problems. But we planned on what we could do, a ship running aground with 600 million gallons of oil. We learned in April of that year that you can have an uncontained spill, with the new Horizon. I do believe it is planning for, as Dr. Lurie said, sometimes the unimaginable and then exercising those plans.

Senator HASSAN. And then making sure there is communication about what you learned.

Mr. NIMMICH. That is right, the policy and the funding.

Senator HASSAN. Thank you.

To Dr. Gerberding, as former CDC Director, you understand the importance of communicating effectively with the American public. As you know, there was some who are concerned that vaccine hesitancy may begin to impact our vaccine administration efforts in the coming weeks. What steps can we take now to improve public confidence in existing COVID-19 vaccines so that we can vaccinate at a rate that mitigates the threat of emerging variants? How do we

communicate the importance of vaccination as critical steps toward reaching herd immunity?

Dr. GERBERDING. Thank you so much for bringing this up, because as I am sure you know, at baseline we deal with a severe crisis in vaccine confidence in the United States and elsewhere, so this pandemic has brought that to the forefront in every way.

The good news is the efforts so far, which particularly emphasized reaching into the communities and constituencies that have the greatest degree of concern and bringing not just scientific information facts and figures, but the messages and the engagement of people they trust. Sometimes at the community level that is a pastor or a barber, or it may be the front-line primary care provider. But we have to build out a network of people who have the facts, but also have the trust of the community.

In many communities the government is not the most trusted part of the equation, nor are the manufacturers of vaccines. This is a matter of all of us affecting—in my company, at Merck, we are working hard to build confidence among our own employees. We are working with the World Economic Forum (WEF) to help employers understand how they can inform their employees and help them make the right choice about vaccination. I think it is an uphill battle, and we are pleased with the support and the supplement to help the CDC lead that communication effort. At the same time, we have a long way to go before we really achieve herd immunity on the basis of vaccination because of the reluctance of so many people. Whenever there is a safety concern, people really struggle to put the very high risk of COVID into the context of low but real potential risk from immunization. It seems like the risk of the vaccine looms so large in your mind, and yet the risk of COVID is deadly to far too many people, and we have to help folks recognize that this is a really important tool, especially if we use it right now.

I would love to talk with you offline more about this because I think there is much more we can and should do.

Senator HASSAN. I thank you because you really answered my next question, too, about how do we get to communities where the skepticism is the greatest and that have traditionally and historically faced the biggest challenges in access, too. I will look forward to that. I thank you so much, too, for pointing out not only the risk of death from COVID but also the long-term risks for long-haul COVID patients compared with the low risks of vaccine.

Thank you, Mr. Chairman, and, last, I will just say to Mr. Nimmich, you can expect a follow-up question from us on how do we make sure that we have the kind of surge capacity we need as we move forward with FEMA having more and more responsibility as that kind of lead emergency agency.

Thanks again for the hearing.

Chairman PETERS. Thank you, Senator Hassan.

Senator Hawley, you are recognized for your questions.

#### **OPENING STATEMENT OF SENATOR HAWLEY**

Senator HAWLEY. Thank you, Mr. Chairman. Thanks to the witnesses for being here.

Ms. Zimmerman, I would like to start with you, if we could, and discuss the supply chain issue. I noticed in your written testimony your recommendations about logistics and just-in-time manufacturing, saying that they do not really work in your experience and observation when we are in the midst of a global event like the one we have just gone through. I certainly agree with that, and I am wondering if you can just elaborate about your experiences at FEMA. What demonstrated to you that the just-in-time model is insufficient for a major crisis like the one that we have just gone through?

Ms. ZIMMERMAN. Right. Thank you, Senator. The just-in-time, when we are working especially in the medical supply chain, medical supply to hospitals, what we have noticed is that they do not have supply on hand for much more than a few days. They require the just-in-time to replenish. They have their contracts so that they can get the supplies they need for their day-to-day operations come in, and they do not have to also have a huge warehouse to store them in. They rely on the private sector for doing that.

So being able to get those commodities when you need them in the extreme amounts that we did during COVID in early days before manufacturing can get pulled up, it made it very critical, and that is when we saw that, there were not supplies within the United States. We needed to go elsewhere. We needed to go to other countries and when it was set up to bring in the commodities from other places.

So the just-in-time can work fine in smaller events, just like the FEMA distribution centers that they have across the country, that stockpile of the water and the blankets and the things that we need to protect lives and get things stabilized during normal natural disasters that FEMA works in. But when it really comes to a global event like this, just-in-time does not work when we do not have manufacturing ready to go to bring in those commodities in the numbers that were needed.

Senator HAWLEY. I have been an advocate of reshoring our critical supply chains and introduced legislation to do that, and I think it is absolutely something that we have to pursue and make a top priority. But you and I both know that that process of onshoring will take time. It is vital we do it, but that is a medium-to long-term project that we need to start now. In the short term, do you have any recommendations about how we can reduce our reliance on the just-in-time model and improve our resiliency in the midst of a major crisis? What can we do immediately that will have short-term implications or effects?

Ms. ZIMMERMAN. I think immediately we need to look at what supplies are on hand. We look at the Strategic National Stockpile when it comes to COVID or any other pandemic and medical issue, looking at those types of things. We try to plan for those maximum of maximum events so that we have things when they use the Defense Production Act to change over manufacturing from cars to ventilators and that. How do we really do that? But what are those key critical things that we need? I think after the last year, we saw the PPE and the supplies that were needed by the medical first responders. We need to make sure that we have a way of getting

those within those country and how we stand up those abilities immediately when we see something happening.

I think this is an opportunity right now. We are still in the midst of the COVID-19, and where are we now with getting commodities in and how we have resourced and been able to get things even for the American people, the masks that people are wearing, the other supplies and things that we need, so looking at where we are today, and we need to accept where we are today, but what are those other things that we might need going forward? We need to be prepared to supply those.

Senator HAWLEY. Very good. Thank you.

Mr. Nimmich, let me just give you a chance to weigh in here given your experience at FEMA. Do you have a view on the supply chain question, whether that is stockpiling, as Ms. Zimmerman just said, stockpiling commodities or ramping up production on a temporary basis or something different?

Mr. NIMMICH. Not dramatically different, Senator, but you could tell from my body language, yes, I have some pretty strong opinions on the ability to move from just-in-time, and the National Stockpile is a good thing, but it is not the only thing we can do. While we are bringing ashore the capacity and being able to understand the Defense Production Act and how we would utilize that in a future capability, we can incentivize hospitals and local medical capability to go over their efficient level, to be able to bring in and actually rotate the stock of medical equipment so that if it is in the National Stockpile, it does not go stale on the shelf and then have to be replaced at a larger cost.

I think we could look at ways of incentivizing hospitals and medical facilities to keep 110 percent of what their daily requirements are, and that 10 percent, if we incentivize it, the Federal Government or the States could reallocate to other areas. You have now distributed your stockpile across the Nation, and it is closer to where you are going to need it whenever you need it.

Senator HAWLEY. That is good. That is very interesting. Let me ask you about the Supply Chain Stabilization Task Force led jointly by DOD and FEMA, which the last administration helped set up—or did set up to help coordinate and maximize the procurement of things like PPE. How well do you think that worked? What should we learn from that experience?

Mr. NIMMICH. Like any task force, it took time to establish itself understand each other's roles. When you again look at the Department of Defense, they understand the National defense industrial base. They know where the capabilities are. We do not try to create a comparable industrial base that we understand and we maintain, and it goes to your bringing back to shore the infrastructure to be able to do this.

I think the task force performed admirably once it had been established and they understood each other's roles, but you have to have, like DOD does, the infrastructure in place to understand how you are going to do this before an event. Creating it during the event reduces that time to perform.

Senator HAWLEY. Very good.

Dr. LURIE. Let me just try to jump in here for a minute, if I could, with one additional suggestion, and we experienced both

shortages in H1N1 and Ebola and found that in different places in the private sector and in government there were actually large supplies that were double and triple ordered, but the government did not necessarily have the mechanism to go to all the manufacturers and distributors and ask where it was in the system. So clarifying authorities for it to be able to do that in an emergency, you can see where it is and redistribute it quickly, I think would be very helpful.

Senator HAWLEY. That is helpful. Thank you.

I see my time has expired. I will have a few more questions, Dr. Gerberding, for you and, Dr. Lurie, for you as well for the record.<sup>1</sup>

Senator HAWLEY. Thank you, Mr. Chairman.

Chairman PETERS. Thank you, Senator Hawley.

Senator Rosen, you are recognized for your questions.

#### **OPENING STATEMENT OF SENATOR ROSEN**

Senator ROSEN. Thank you, Chair Peters and Ranking Member Portman. This is a really important hearing, and I appreciate all the witnesses for everything you have done and for being here today.

I want to talk a little bit about data tracking and early pandemic response. As we know, the pandemic dominated American life last year and, of course, into this year. Our focus has rightly remained on tackling the immediate challenges before us. We have to work to save lives and livelihoods.

However, I do think there were missed opportunities to get a better picture of the pandemic, which is critical to understanding how to protect people dealing with the long-term effects of COVID, making sure we are not leaving anybody behind.

So moving forward, I believe we need to be sure we have a comprehensive understanding of priorities while still doing research efficiently so that data collection does not delay us getting help to those who need it, it is not so cumbersome, because a novel virus like COVID-19, it is critical we have a full understanding of the impacts. Only through data collection is it going to tell you that.

Last year, I introduced the bipartisan Ensuring Understanding of COVID-19 to Protect Public Health Act. I want to make sure we get started on those comprehensive long-term studies with regular reporting right away so that researchers and clinicians can have the latest information. Some of the studies have started, but, of course, there are significant gaps. I hope all my colleagues will join me.

But, Dr. Gerberding, can you please discuss some of the remaining gaps in research we have, especially now that we are seeing the long haulers, people who are in it for the long term, they seem fine and things are popping back up? How does the virus seem to be impacting patients differently, especially so we need to do research on this?

Dr. GERBERDING. We have a lot to learn, to start with the medical dimensions of the infection. You are absolutely right. We do not really understand the actual pathogenesis or the mechanism by which this virus causes such a myriad constellation of diseases, ev-

<sup>1</sup>The questions of Senator Hawley appears in the Appendix on page 83.

everything from no symptoms all the way to devastating multi-organ system failure. Some of that is perhaps related to viral load; some of it is genetic. But there is much to be learned there, just at a very basic medical level.

But, in addition, the syndrome of the post-infectious phase of COVID, which is increasingly recognized as the broad constellation of findings with a pretty durable impact on people, not just their physical health but their mental health and their ability to function, we have to understand this post-infectious phase of illness. But I think there are also many things that we need to learn about the basic epidemiology, and, again, that is where data systems can be our best friend because we may be able to probe things from existing data or more rapidly get our hands on data that are evolving through our health systems and our public health systems to be able to draw connections and see patterns that we cannot currently recognize without the use of artificial intelligence (AI) or machine learning-type tools.

The list of what we need to know is long. I think right now everyone is kind of focused on the most critical things in the context of care of patients and vaccination, but we are going to be with this coronavirus for a long time.

Senator ROSEN. I agree with you. The list is long, so we need a vast amount of information, but we need it quickly. I have heard from some caregivers up and down my State, especially in smaller, more rural areas. They are hesitating on some things because they do not know if they have the capacity to comply with the various reporting systems.

How do you think we need to simplify the process so that everybody getting vaccinations and treatments in our community health centers, in our smaller hospitals, that we have the interoperability and the ease of reporting so we can get vast amount of data to us quickly? Dr. Lurie and Ms. Zimmerman, maybe you might respond to the collecting of data and the interoperability to give the doctors the tools they need going forward, give us all of us really.

Dr. LURIE. Sure. I would say a couple of things. First of all, it got going late, but there are now mechanisms through something called "Project Echo" to pull doctors together every week for sort of peer-to-peer learning about best practices and how to treat one another. I would encourage all kinds of health care providers to take advantage of that.

But make no mistake. Our data systems are really siloed. You are right; they are not interoperable. In fact, there are vast amounts of data out there that go unanalyzed because we do not have the tools to do it and we do not have the workforce to do it.

Going forward, I think we could ask ourselves very fairly now, what needs to be done by humans? Or could you have sort of early aberrant signals picked up now by machine learning, by artificial intelligence, and others, so we could put the highly trained human capacity where it needs to go and not miss signals and be able to aggregate data much more quickly? On the data end, we have made such great progress from the perspective of integrating it or health care and public health data together into the way we understand the disease and the way we make decisions. We have a really long way to go and a huge opportunity there to do better.

Senator ROSEN. Thank you.

Ms. Zimmerman, what do you think we might be able to do to help improve this interoperability between, I guess, I want to say “partners,” whether they are health care, FEMA, community partners, mobile clinics, you name it, hospitals, all of our system? Do you have suggestions for us?

Ms. ZIMMERMAN. Yes, thank you, Senator, exactly, because when you start chasing the data—and in the beginning of COVID-19 everybody was chasing all sorts of data. There was no set parameters of what was needed to make decisions. In the beginning you are making it with limited data, and that is what emergency managers do. They go forth and push.

But I think we have a great opportunity right now to look at what data provided us the best information in order to make those decisions. What are those immediate decisions you need to make at the onset of a pandemic or any type of major medical thing that is impacting the Nation? I think it is looking at what were the things that gave us the outcomes. To me, you need to look at the outcomes and what is the data needed to get that and to be able to put the smart people in the room to determine what is needed in that regard I think is very key right now, because, otherwise, with all of the technology and everything that is out there, we go chasing a lot of data points that do not give us an outcome that matters, and we need to look at what are those outcomes that are going to matter to shortening the time period for all of this that we have been through.

Senator ROSEN. Thank you. As a former analyst, I could not agree more that the data tells a story if you figure out how you need to listen to it, and we really need to understand the lessons we have learned that we can use, not just for going forward in this pandemic, but God forbid we have another or the next public health emergency. So this should be able to guide us.

Thank you. I will submit the rest of the questions for the record.

Senator ROSEN. Thank you.

Chairman PETERS. Thank you, Senator Rosen.

Senator Johnson, you are recognized for your questions.

#### OPENING STATEMENT OF SENATOR JOHNSON

Senator JOHNSON. Thank you, Mr. Chairman.

Dr. Gerberding, first of all, welcome back to the Committee. I remember you testifying before our Committee on February 12th on many of these same issues. I am sure we talked about testing. I want to talk a little bit about that. But I know it was in that hearing that I found out, because FDA Commissioner Gottlieb also testified, about our lack of active pharmaceutical ingredient (API).

As I further investigated that, I found out there is something even before API, which is what they call “intermediate.” It is an odd name because it is really the precursor chemicals. It sounds like most of those precursor chemicals, because it is a dirty manufacturing process, occurs in China. Is that accurate?

Dr. GERBERDING. I think it depends on what product you are talking about, but the global supply chain that is the raw materials, the intermediates, and the API, certainly includes China, India, and many other locations around the world.

Senator JOHNSON. But if we really want security in terms of our pharmaceutical industry, we really need to get not only API back in the United States, but we are going to have to do that, the intermediate, the precursor chemicals as well, and we are going to have to figure out how to do that environmentally safely. Correct?

Dr. GERBERDING. I think the safety and the fidelity and the consistency of the supply are really critical issues. All of us in the context of COVID have been examining our supply chains, not just for vaccines and the most critical countermeasures, but for our entire supply chain, many companies have a system of having kind of a bubble, sort of what we were talking about with the Strategic National Stockpile, so that we have a contingency planning around those intermediates. But our vulnerabilities are clear now, and we are going to need to do more to make sure we can sustain the most critical essential medicines and vaccines in times of international stress.

Senator JOHNSON. Let us talk about testing. February 4th, we were still pretty early into this pandemic. I think everybody recognized we would like to get tests so that we can identify cases so we can quarantine people. It took many weeks, a number of stumbles. I guess maybe it is my manufacturing background where I am a little more sympathetic that these things just are not that easy. It takes time to ramp up manufacturing. You need basic supplies. We found out—just glass vials, we needed the reagents, we needed the chemicals, that type of thing.

So the question I have is: Assuming we could have immediately get a test that worked, and even that, I mean, it is nice to be a Monday morning quarterback, but we did not even have the pathogen, we did not even have the virus. I do not know how much better we could have done, maybe a few weeks. But what do we need to put in place today, what supplies do we need to keep in the National Stockpile or through a private sector distribution system where we maybe pay people to carry excess inventories? Do we need glass vials? Do we need certain chemicals? What do we need so we can prepare and be testing earlier next time?

Again, I am not sure we could have done that much better. Maybe by a few weeks. I think the horse was out of the barn at that point in time. I think we maybe overstate the case in terms of how the pandemic played out. But what do we need in terms of testing supplies?

Dr. GERBERDING. First of all, this is a perfect storm, much asymptomatic disease, so who do you test? You cannot test 300 million people all at once, so that really challenged everyone, even, as you said, with the perfect test available to us.

Second, scaling a test quickly depends not only on the ability to make the test kits and deploy them; it also depends on having the samples of known cases so that you can determine if the test is actually reliable or not. And that was a gap that I think Dr. Lurie has already mentioned.

The third thing I would say about testing per se is that I worked at the CDC for a long time, and I have watched them before and after, and CDC is actually extremely good at making tests for new pathogens. So this problem in this situation was tragic, but an isolated situation, and I know there are going to need to be specific

remediation steps. But going beyond that, I think to solve this problem in the future, we have to plan ahead for how we bring in the private sector right at the beginning and have the consortium of people available to work collaboratively.

I do not think the testing issue is so much a supply issue per se as it was simply the ability to validate and prove the reliability. Of course, we have had a lot of bad tests come out, and we have had some counterfeit tests come out. That is a whole other set of issues that we kind of had to contend with.

Senator JOHNSON. Again, it is fine to be a Monday morning quarterback, but I think we need to be a little careful. Back in 2009, with H1N1, CDC in the end estimated somewhere between 43 and 89 million people got infected with H1N1. Right now we are about 31 million. To a certain extent, we have flattened the curve by what we have done. I think we need to actually take a look at the numbers. I have been tracking the numbers very carefully. Deaths per million, Italy, about 2,700; U.K., about 1,870—these are as of April 1st. The United States, we are at a little under 1,700. Everybody criticized Sweden for—not everybody. I did not—for a different approach, isolate the sick, quarantine the sick, protect the vulnerable, and then have the rest of us go about our lives as carefully as possible. They are below us at about a little over 1,500. But, I want to see if anybody can explain why is India at 120 deaths per million when all these U.S. and European countries are well over 1,500 deaths per million? What is the difference?

Dr. GERBERDING. Many differences, but one of them is that testing is even less available in India. The infrastructure of public health there is even more impaired, many billions of people that are not necessarily accounted for are included in those numerators and denominators, and India—

Senator JOHNSON. So you question the numbers on that one?

Dr. GERBERDING. I am sorry?

Senator JOHNSON. You are questioning the numbers they are reporting.

Dr. GERBERDING. I think—

Senator JOHNSON. I have no idea.

Dr. GERBERDING [continuing]. But India also right now is the leading edge of surge on a global basis, so they are coming into—

Senator JOHNSON. A stark difference, 120 deaths per million versus—I will try to get an explanation on that.

The final question I have is: I think we have to factor in the human toll, the cost, the economic devastation of these shutdowns, and really ask ourselves what was worse. We had Dr. Bhattacharya testify before our Committee talking about a WHO study that said there were 130 million people at risk of starvation. I think we have to within our pandemic planning, next time we jump to shutting down our economy, I think we have to also understand the human toll of these shutdowns. Would you agree or disagree with that?

Dr. GERBERDING. I think when you are looking at now 563,000 deaths in America, it is hard to feel good about that—

Senator JOHNSON. I am not saying we should.

Dr. GERBERDING [continuing]. Under these circumstances, so, we need to understand the full ripple effects. But, clearly, the social

distancing and the isolation, the devastating economic circumstances have their own toll. There is no doubt about it. One of the most important dimensions of that is that people are not getting their ordinary care. We are not vaccinating our kids, we are not taking care of our diabetes, we are not screening for cancers. These are things whose toll with accumulate over a much longer period of time.

So, yes, this is a very wicked problem we are trying to solve here. The most important thing is to contain the virus as quickly as we can.

Senator JOHNSON. OK. Thank you, Mr. Chairman.

Chairman PETERS. Thank you, Senator Johnson.

Senator Ossoff, you are recognized for your questions.

#### **OPENING STATEMENT OF SENATOR OSSOFF**

Senator OSSOFF. Thank you, Mr. Chairman. Thank you to our distinguished panelists.

Dr. Gerberding, I want to thank you as well for your service and leadership of the Centers for Disease Control and Prevention, which, of course, as you well know, are located in my home State of Georgia. We have such an outstanding team of public health professionals, medical doctors, and civil servants who lead our Nation's epidemiological efforts and disease control efforts.

Dr. Gerberding, based on your experience and your assessment of what has gone wrong and what has gone right over the last year and a half, I would like to ask you to take this opportunity to make recommendations to this Committee and to the Congress with respect to how we can empower and resource the CDC to augment its capacity, empower its nonpartisan public health professionals, and make more robust our national capacity to adapt and respond to a pandemic.

Dr. GERBERDING. Thank you, and I will follow up with you because we are exploring this issue with the CSIS Commission on Global Health Security as well. But there are some big buckets here.

First is structural. I think we have seen that it is very possible for the CDC science to not have the role it needs to have in planning and responding to a serious health threat, and that just cannot happen again. Scientists need to be able to bring the science to the policymakers unfettered.

Secondly, there are structural issues related to the way the CDC is funded. The budget is inconsistent from year to year. The crisis-to-complacency cycle—"boom or bust" some people call it—results in unstable funding. It is very difficult for State and locals to hire the people they need. It is very difficult for the CDC to sustain progressive preparedness over time.

Then I think the third issue really is certain parts of the CDC science need to be modernized. We are kind of in a stable level of support, but science is bursting ahead, and we need to bring the more modern tools, the data sciences, the data information modernization. There are a whole number of areas of scientific inquiry relevant to public health. We need the same kind of funding support that we give to NIH and biomedical research, but that is, a

long-term investment, and we are really going to need congressional support for that. So thank you for the question.

Senator OSSOFF. Thank you, Dr. Gerberding. Let us talk a little bit about effective public health communication and how we can improve public health experts' capacity to deliver evidence-based information to the public, to families, to organizations, when you have an emerging situation such as we did where there is uncertainty and fear, particularly in the early months of this pandemic, and where you have political actors with no relevant public health expertise, such as in this case the President of the United States speculating about the efficacy of bleach treatments in response to COVID-19 from the White House Press Briefing Room. How can we enhance the capacity of public health experts and medical doctors who are qualified to assess the available data and make evidence-based recommendations to the public, acknowledging that there will always be uncertainty, particularly when we are facing a new pathogen whose means of transmission and lethality and mechanism of action is not yet fully established? How can we enhance our ability to deliver evidence-based information from public health experts to the public in an emergency such as this one?

Dr. GERBERDING. There is no question to that misinformation, in many cases disinformation is easy to propagate now, and it has tremendous impact on people through the expansion in the social networks that perpetuate it. This has to happen at every level. Trust is the foundational dimension of this.

When people see scientists arguing with each other about data, that in and of itself creates mistrust. In the context of the rapid learning curve we are in, sometimes that is inevitable. But I think the CDC Director today, Dr. Wollensky, is doing a fantastic job of persistently saying the same thing, standing strong, speaking regularly and often, doing the best she can to translate evolving information to the public. But that has to be cascaded throughout our whole system.

We learned during some of the outbreaks that I managed that the most trusted person for most people is not their Federal official or their politician or even someone who is pontificating on boxes on the network news. It is their local doctor. And so bringing the clinician community into the knowledge base to share that evidence and giving them the tools and the training they need to help translate it is also critically important.

I think we have seen that done well in other countries like New Zealand, but we need to go back to basics and restart our process of getting the whole ecosystem of trusted health officials to sing from the same sheet of music and translate that information into messages that matter to people.

Senator OSSOFF. Thank you so much, Doctor. Thank you all for your testimony today, for your service, and for the expertise and experience you have shared with us.

Mr. Chairman, I yield.

Chairman PETERS. Thank you, Senator Ossoff.

We may have another Senator or two. We are about ready to start votes, and, folks, we have multiple committees so we may have another Senator or two arrive. In the meantime, I am going

to take the liberty as Chair to ask another couple questions while we wait.

My first question, I am going to put it out to the panel to give me a sense. One thing that is clear as we have gone through this critically difficult time is that there are many conflicting authorities, and we have talked about that throughout this hearing. So although it is clear there are conflicting authorities, there is no clear path as to who should actually be in charge. You think about the multiple laws right now that we have on the books that determine disaster and public health emergency response authorities. We have the Public Health Services Act, the Stafford Act, the National Emergencies Act, various Homeland Security Presidential Directives, Presidential policy directives, and that list, unfortunately, can just go on.

I will ask this to you first, Dr. Lurie, but I would certainly love to have the input of all of you. Dr. Lurie, I ask it first because you already testified about the need for a clear Federal agency to lead in pandemic response. Yet from this initial COVID-19 response, there was continued confusion. There were changes in authorities as we went along.

So it is a very direct question. Who at the Federal level should have led the response, in your mind, for this public health crisis? I would love to hear from the other panelists as well.

Dr. LURIE. Sure. I think the White House should have designated a lead at NSC supported by FEMA to lead this and pull together a whole-of-government response as they have for so many other crises. As Mr. Nimmich testified and Ms. Zimmerman testified, FEMA can help coordinate and support. At the beginning you do not even know how bad it is going to be, and it evolves over time. And so it may be that the lead in coordination needs to evolve over time. But there is no reason not to mobilize a whole-of-government response, and there are many mechanisms to do that. You just have to choose one.

Chairman PETERS. Great. Anyone else? Just jump in, please.

Dr. GERBERDING. I will say I think the whole-of-government is the concept, although it is more than government, as we have seen; the private sector is critically important, and the whole health system matters in a situation like this. But the concept of planning for the whole-of-government, the strategic framework for the operation being something that really has to be done by the administration because all the Cabinets are involved, and then executing the components of that plan in the agency that is best suited to carry out the specific tasks or objectives at hand. It is kind of plan horizontally, execute vertically, and then maintain that coordinating function.

From an operational and logistical perspective, I think the FEMA conversation can also come into play here, especially when there are issues about deployment of material goods or getting things moved around from one place to another. So there are many different dimensions of the operation, but the strategic framework, the intent of the response really needs to be centralized, in my opinion, in the White House.

Chairman PETERS. Right.

Mr. NIMMICH. Chairman, I have to respond that the National Response Framework gives you the ability to do this, and as Dr. Lurie will attest, FEMA supported HHS in Flint, Michigan; we supported HHS in the Ebola outbreak; we supported HHS in the Zika outbreak. The ability to use the infrastructure and the response, training, and professionalism inside FEMA—it does not have to be in charge, but you have to make that clear. I do think there was a stumble when we said HHS was not in charge and now FEMA is in charge. It should have been HHS is in charge and FEMA is the supporting entity that is implementing HHS' knowledge base of the pandemic.

Dr. LURIE. I would agree.

Chairman PETERS. Ms. Zimmerman.

Ms. ZIMMERMAN. Yes, and I agree with what Mr. Nimmich has just said. This is something FEMA does. They do it for all disasters all the time. The system that is in place within the NRF and within the National Response Coordination Center, all the Federal agencies, voluntary agencies, even the private sector is very familiar with how that works. And to be able to employ that very quickly during disasters is key. It does not matter how big or small. It is practiced all the time. State level, States have set up their emergency operation centers much the same way. So it is really something that gives people that opportunity to jump right into events, and I think doing that but I think being led by the agency that has the known mission set such as any pandemic, with HHS being the lead for that, and then how, in this event they established the Unified Coordination Group (UCG), which was the first time ever at a national—at the Federal level, to establish that I think was key. I think just to keep that in the forefront is very important going forward.

Mr. NIMMICH. Mr. Chairman, if I could have another opportunity?

Chairman PETERS. Yes.

Mr. NIMMICH. I do think that the challenge is deciding if you are going to activate the National Response Coordination Center at FEMA. I think that there should be a much more robust interface of all the departments, particularly ASPR and FEMA, on a day-to-day basis. It should not be when we make a decision that we have crossed the threshold that we now activate the NRCC. There needs to be—each of the emergency support functions needs a day-to-day connectivity in the environment we are in because things happen so quickly.

Chairman PETERS. Very good. Mr. Nimmich, I am going to ask you a question. In your testimony you discuss the need to create additional surge capacity for supplies in an emergency, and you recommended this responsibility be given to a new FEMA surge center. So my question to you is: What additional authorities and funding, if any, do you believe that this center would need if we were to set it up?

Mr. NIMMICH. I think, Chairman, this goes back to the ability to access all those silos of data Dr. Lurie talked about, and it is not just in the medical side, but it is in the supply side and the demand side of these. We often protect our data or do not want to trust our data, so that surge center would create an environment

where we can have data that is protected, not utilized in a way that the provider of that data would not want it. So the public sector can bring in and tell me there is excess capacity of PPE at this location and know that that is being trusted and will only be used when there is a need nationally, or we can inform another State or another county that that capacity exists somewhere and they can access it.

But that does not exist. It will require additional authorities to allow FEMA to integrate that data. It can be done with medical data, as well as Dr. Lurie pointed out, and it will require improvement in technology. The technology exists today. Whether it is in how we protect our information but also access our information, we have the technology now to be able to access all of that. The artificial intelligence will start us to be able to be smarter of where we put our human capability. But it is really a center where you can bring that data in on a day-to-day basis and add to it. I was not monitoring how much of the precursor elements were needed for our pharmaceuticals. Now I want to access that information and understand where those precursor chemicals come in.

Chairman PETERS. Great. Thank you.

Senator Padilla, you are recognized for your questions.

#### OPENING STATEMENT OF SENATOR PADILLA

Senator PADILLA. Thank you, Mr. Chair. Thank you to all the witnesses for your participation and your testimony today.

As several of our colleagues have raised throughout the course of the last year, I want to ask questions specifically concerning the aspects of COVID-19 and its disproportionate impact on communities of color and lower-income communities. And just using my own home State as an example, in California the death rate for Latinos is 22 percent higher than the statewide average. The case rate for Pacific Islanders is 32 percent higher than the statewide average. The case rate for communities with median incomes below \$40,000 a year is 37 percent higher than the statewide average.

COVID-19 has clearly exposed large underlying racial and socioeconomic disparities in our health care system, in our pandemic response plans, particularly at earlier stages, and the disproportionate risk for essential worker populations.

So a question for Ms. Lurie and Mr. Nimmich. How can we ensure that our pandemic response plans and our disaster response plans more broadly take into account these underlying issues of inequity?

Dr. LURIE. It is such a terrific and important question that needs to be considered really comprehensively. We talked a lot earlier about planning, and certainly racial and ethnic minorities and low-income communities and others need to be involved in the planning process from the get-go. They need to be understood. Every single time we think about doing surveillance, that we think about doing data collection, that we think about getting a complete picture of what the situation is, we need those sort of data elements about race, ethnicity, income, social vulnerability index of where someone lives. Frankly, that has to be a reflex part of every single bit of analysis so that we can identify as quickly as possible the popu-

lations that are the most adversely affected and address them as quickly as possible.

But, also operationally, you have to have representatives of all of those communities with you at the table and part of the operational plan to get going. In a nutshell, it is just end to end looking at everything you do through this lens of equity.

Mr. NIMMICH. Senator, it is one of the toughest questions that we have to deal with, and it is a challenge. It is a community—the underserved and economically disadvantaged tend to have less trust in the Federal Government, tend to have less trust in what is being said. We need to encourage them to participate in the planning and the understanding. But we need to reach out to those community leaders that are able to explain.

I can tell you from a FEMA perspective the ability for that community to request the assistance that they deserve is often limited. They do not even understand that there are opportunities there for them to take advantage of.

Finally, when they do take advantage, they are often put in difficult situations, multiple different questions, multiple different programs. I am registered for a State program, a Federal program, and it becomes overwhelming for them to be able to participate and provide the details that we as a government require before we are willing to give out aid.

Senator PADILLA. Thank you. What leads to that question is a recognition of what the data is telling us. So my next question for a couple of you is not just underscoring the value of data but fundamental science. Many of you have mentioned in your testimony science is the foundation of our response measures to disasters. Science and research guide the public health recommendations and directives, including during COVID, social distancing, masks, face coverings, vaccine stations and distribution plans, et cetera. So without basic research done through NIH-funded institutes, our responses and vaccines could have taken much longer to develop and complete.

Ms. Lurie and Ms. Gerberding, could you both comment on how we can more effectively use research from the COVID-19 response to improve our responses to future disasters and pandemics and what kind of data might have been more helpful earlier in the pandemic as, again, a case study to inform future emergencies?

Dr. LURIE. Sure. One of the first things I would note is that in prior crises we have pulled together early and often with the help of the National Academies, developed a research agenda that prioritizes the most important questions to ask and answer as a country so that we can get on top of that quickly. Unfortunately, that really did not happen.

A second thing I would want to note is that science includes social science, includes anthropology and sociology, and, here I think we missed for a long time, as Mr. Nimmich was pointing out, the way different population groups were being impacted by this. I think social science brought to bear early on would be critically important.

Then, third, as I said, always look at the population subgroups that you think are going to be the most vulnerable, and sometimes you are surprised about who they are, but to be able to have that

ability to do that. We have to be able to continue to fund science, and we have to be able, as I testified, to protect the integrity of our science agencies, to do science and to speak the truth about results. I think that last part, while we have not dwelt on it, deserves a lot of consideration.

Senator PADILLA. Thank you.

Dr. GERBERDING. Yes, I will add to what Dr. Lurie said because I agree with her entire statement and especially the component of the National Academy of Medicine contribution to setting the research agenda, is that we need practical science as well, just nuts and bolts, like: Do masks work? It took us a long time to really establish that this was an aerosol virus, and that is something that, had we set about finding that information early in the course of the situation, we might have been able to have better guidance up front about the importance of masks and what kinds of masks and how well they work, et cetera. There is a whole set of practical questions that come up in any outbreak, but were certainly critically important in this one, especially with the large degree of high-titer asymptomatic infections.

I think a second aspect of this really relates to how we can build the science of the new tools that we need, as mentioned earlier, the data tools, the artificial intelligence machine learning that can take advantage of the information that we do have and create knowledge out of it.

The third thing I would say, for a long time there has been a paucity of investment in what I would consider to be public health research. Not all of the research done at the NIH is germane to some of these practical translational problems that I am talking about, and CDC does really need a bigger research budget so they can get the best and the brightest people in our academic environment, our medical schools, our schools of public health, our social science schools, to get on to some of these issues and really build out the science base. It will serve us well in the short run in this context, but it is something that we need foundationally going into whatever the next new emerging infection is.

Senator PADILLA. Thank you both.

Thank you, Mr. Chair.

Chairman PETERS. Thank you, Senator Padilla.

We are going to be wrapping up this hearing. This has been fascinating. But I do have one last question for Dr. Lurie, and then we will wrap this up.

Dr. Lurie, in your testimony you discuss the need to gain additional visibility into the medical supply chain, and you noted in that testimony that during the H1N1 and Ebola epidemics, HHS put together a system to gain visibility into the supply chain, which is critical. As part of our Federal preparedness, as we are looking forward, should the U.S. Government establish as part of its infrastructure a permanent system to track medical supply chain? And as you are thinking that through and with an answer, what limitations currently restrict ASPR's visibility into the supply chain that we need to be aware of?

Dr. LURIE. Terrific question, and I think obviously, as we have talked about at this hearing, we have talked about precursor material; we have talked about API; we have talked about all kinds of

supplies. And, yes, we absolutely do need to have visibility into all of the critical elements of the medical and health care supply chain. This goes from essential medications all the way, as I think in my written testimony I talked about the pipette tips and the little laboratory wells that are important for running the diagnostic tests.

The Strategic National Stockpile has traditionally only had visibility on what is there, and yet we know that there is a lot more in the supply chain. We know we have critical drug shortages every year, and we do not do a good job monitoring those either. So, yes, I think either a system that Mr. Nimmich outlined or the Strategic National Stockpile needs to build the capability to have that visibility and monitor critical health and medical supplies.

When we did it in H1N1 and Ebola, we did it using the threat of the Defense Production Act to ask manufacturers and suppliers to share the information, and we are able to keep it confidential so we did not disrupt their businesses. But this is an area where I do think new authorities and funding will be really important to set up this system so that you know what you need and can track that day to day and that you have enhanced ability to track and, if needed, voluntarily or compulsorily redistribute in an emergency situation. It is going to be a big lift and a big build, but the whole private sector of our economy does this very successfully every day, day in and day out. And there is a lot of expertise and tools to use out there to build such a system. It is critical.

Chairman PETERS. I agree with you, and it is clear from your statement that you do believe there are additional authorities that are necessary, so legislative action will be necessary?

Dr. LURIE. Yes.

Chairman PETERS. Very good. We will look forward to talking further with you on that. We are in the process of drafting some of that, so we will look forward to working with the details.

Again, I want to thank each of our witnesses today. This was just a great hearing. We have an awful lot of information. Clearly, there is a whole lot more information to gather in the months ahead as we continue to look at what happened and think through how we can do it better.

As I mentioned at the beginning of the hearing, we always want to celebrate our successes. We should do that. But we also need to find out where the failures were and make sure that we are plugging those gaps, and that is the intent of what we want to do in this hearing.

With that, the hearing record will remain open for 15 days until April 29th at 5 p.m. for the submission of statements and questions for the record. This hearing is now adjourned.

[Whereupon, at 11:58 a.m., the Committee was adjourned.]

## A P P E N D I X

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**Chairman Peters Opening Statement As Prepared for Delivery  
Full Committee Hearing: Preparedness for COVID-19: The Initial Pandemic Response and  
Lessons Learned  
April 14, 2021**

First, I want to thank each of our witnesses for joining today's important discussion, which will be the first in a series of hearings focusing on the federal government's preparation for, and response to, the Coronavirus pandemic.

We have to examine and confront our failures, identify and build on what went right, and propose reforms to ensure our nation can combat this pandemic and be better prepared to prevent and respond to future pandemics and public health threats.

I appreciate Ranking Member Portman for joining me to conduct bipartisan oversight of the federal pandemic preparedness and response efforts. This approach is a clear example of how this committee is stronger when we work together.

And no challenge requires a bipartisan approach more than tackling this once in a lifetime pandemic. Since the first cases were diagnosed in the United States, more than 562,000 Americans have lost their lives.

And while Congress has provided critical relief, over the course of this pandemic, millions of Americans lost their jobs, families continue struggling to make ends meet, and countless small businesses are being forced to close their doors permanently.

With more than 4 million Americans getting immunized every day, and the number of deaths from Coronavirus declining, there is a light at the end of the tunnel.

But we are not out of the dark yet. I am concerned that cases continue to rise, particularly in my home state of Michigan.

While vaccines are an important step to prevent the spread of COVID-19, we still need to practice social distancing, wear masks, and follow the advice of public health experts to get the resurgence of this virus under control, especially as variants continue to spread across the country.

Tragically, it didn't have to be this way. The lives lost, the permanent changes to people's personal health, the economic devastation, and the long months of personal sacrifice and suffering were not inevitable.

Adherence to years of pandemic planning by prior administrations, decisive action, and clear leadership from the Trump Administration could have helped mitigate this pandemic.

In fact, since the first whole of government pandemic response plan was published in 2005, the United States has had ample opportunity to prepare for public health crises.

Professionals across our government spent years working to improve our pandemic preparedness, from a pandemic response playbook drafted by the National Security Council in 2016, to a 2019 Department of Health and Human Services series of exercises called Crimson Contagion that simulated a highly contagious airborne influenza pandemic.

In 2019, I conducted an investigation and released a report that identified the serious national security risks posed by our overreliance on foreign manufacturers for critical drugs and medical supplies.

My report found the United States was unprepared to deliver vaccinations on the scale needed during a pandemic, and made critical recommendations that could help onshore manufacturing for essential supplies.

Unfortunately, despite preemptive actions and warnings, the previous Administration failed to take necessary steps that would have limited the impact of the Coronavirus pandemic.

Instead of acting swiftly and decisively, the previous Administration chose to sideline our nation's foremost medical experts and failed to implement a comprehensive national strategy that left individual states to combat the virus all on their own.

In fact, we know President Trump was aware the virus was both deadly and contagious as early as February 2020. However, he continued to tell the American people it would "miraculously disappear" and initially even compared its effects to the flu, when scientific evidence clearly showed Coronavirus was more lethal.

At a time when the Administration could have provided clear and consistent communication – supported scientific guidance on needed public health measures, and ramped up production of PPE and other critical medical supplies through emergency contracts and fully invoking the Defense Production Act, among other critical actions, the previous Administration sought to downplay the virus's severity to the public.

On top of those failures, there have been numerous reports of widespread political interference in federal agencies' COVID-19 response, including reports that Health and Human Services political appointees reviewed and may have altered or delayed weekly scientific reports issued by the Centers for Disease Control and Prevention about the pandemic.

The Trump Administration's inaction and efforts to minimize the threat posed by COVID-19 contributed to the carnage our communities have seen over the past year.

Despite representing only four percent of the world's population, by January 2021, the United States accounted for nearly a quarter of the global COVID-19 cases.

There's no question that the federal government must learn from these missteps and urgently work to strengthen our pandemic response, to ensure we can both combat the ongoing pandemic, and prevent the next crisis, whatever it may be, from reaching this magnitude.

Today, we will hear from former officials from key agencies in federal government, all of whom are widely credited experts in their respective public health and emergency preparedness fields.

I look forward to a frank and open discussion and clear and candid recommendations about what we must do to avoid past mistakes moving forward. It is our duty to ensure our nation is better able to meet whatever the next crisis may be.

Opening Statement of Ranking Member Rob Portman  
“Preparedness for COVID-19: The Initial Pandemic Response and Lessons Learned”  
April 14, 2021

Thank you, Mr. Chairman. I appreciate the fact that our oversight so far – and we have sent a lot of letters and done a lot of interviews – that that oversight has been not just bipartisan, but nonpartisan. And that we have been able to set aside politics, and focus on the facts and past events, but also on the road ahead of us and how we can learn from what happened during this unprecedented, tragic coronavirus situation.

First though, I want to take a moment to acknowledge the extraordinary loss that our nation has experienced. As of this morning, 559,741 Americans have died because of COVID-19. And like just about all Americans, I have lost friends. I have also lost former staff members and we all join with the families in grieving those we have lost during this pandemic.

I also want to express my gratitude for the work and the sacrifice of those who have been on the frontlines. Particularly those health care professionals who have been out there on the frontlines for all of us, 1,541 of whom died fighting this pandemic.

COVID-19 has been catastrophic, there’s no mistake about that. It also presented an unprecedented challenge to, in many ways, an unprepared U.S. public health system. Why were we unprepared? That’s one of the questions we’ll get into today.

Unlike emergencies more localized in nature, a pandemic is not a singular event. COVID-19 has stretched across our entire country, in fact, the entire globe, with no regard for borders or beliefs. The scope is unprecedented. It has stressed our supply and healthcare systems—including our critical frontline personnel as we said — and it has stressed it often to a breaking point. And we have seen the economic damage. Millions have lost their jobs as a result of pandemic restrictions.

We are here today to understand some important issues: the United States’ preparedness and initial efforts leading into the COVID-19 pandemic; the initial federal response; and to identify recommendations to improve federal preparedness for future pandemics and other public health threats.

We owe it to those Americans who did die as a result of COVID-19, to their families and countless others who are struggling to make ends meet to make this a serious, nonpartisan oversight effort. Looking at the steps the federal government took in the initial days of the pandemic, we’ve got to learn from the experience for the future.

To that end, I think there are three issues that are important to address. First, CDC surveillance systems and the lack of testing limited our early response. We know that China irresponsibly downplayed the initial severity of COVID-19. In my view, there’s no question about that. That presents questions about our ability to work with global partners, particularly China, to identify and combat pandemics in their nascent stages.

But, how did we do in the United States at recognizing and communicating COVID-19 cases, symptoms, and deaths, once the pandemic reached our shores? The CDC can only communicate and address the issues it knows about and understands. In many instances, what we found out, is that COVID-19 cases manifested in patient symptoms and were ultimately the cause of death, but that information was slow to reach the CDC. Why was that? Instead of seeing real-time data, the CDC was only seeing fragmented, historical data. Adding to surveillance challenges, diagnostic testing was slow to develop, and then slow to scale up to the level required by the pandemic. Why was that? It is critical that we enable state and local public health officials to communicate effectively and directly to the CDC. We also must have the capability to scale up testing when needed. We know those things. We've got to talk about how to do that better. In a future pandemic, this could mean the difference between quick, life-saving decisions, or confusion, and the needless loss of life.

Second, who was in charge? Where was the accountability? This is something I look forward to asking some of our distinguished panel about today because they have a lot of experience in how these things are managed. The reoccurring narrative in interviews with former government officials, like the ones we have today, and public health professionals is that, in the initial stages of the pandemic, leadership roles were not well-defined and they still are not well-defined, in my view, in some respects. This resulted in confusion at the federal, state, and the local level, and likely slowed our initial response considerably.

But we knew this was going to be an issue. In 2019, HHS ran an influenza pandemic tabletop exercise called Crimson Contagion. That exercise identified the lack of defined leadership as a major challenge. The exercise found that insufficient and conflicting statutory authorities defining leadership roles hampered the federal government's ability to effectively respond to a pandemic. Confusion about leadership was also an issue identified following the 2009–2010 H1N1 pandemic. So this should be a cautionary tale for us as we continue our review: it's not enough to identify issues; we've got to be forward-thinking and actually implement solutions to the issues we discover.

Third, this unprecedented pandemic crippled the U.S. medical supply chain in the initial weeks of the pandemic. Why was that? It was due, in large part, to a longstanding over-reliance on China for pharmaceuticals and other medical supplies, including PPE. Reports indicate that China, as early as December 2019, increased imports and decreased exports of medical supplies as their own needs increased, dramatically shrinking U.S. purchasing ability. Compounding this issue was the lack of an organic medical supply stockpile here in our country.

The Strategic National Stockpile, SNS, which we'll talk a lot about today — the largest federal repository of pharmaceuticals and critical medical supplies, available for rapid delivery to support the response to a public health emergency, was not adequate when those state and local supplies are depleted and it was, frankly, understocked. We need to talk about why and again, how to prepare for the future. The SNS was never replenished, despite urgent requests, after the 2009 H1N1 pandemic, and, further, was never meant for a nationwide response. This, too, was an issue that we knew about. Past pandemic exercises and lessons learned from prior pandemics—such as H1N1—told us that supply chain

resiliency was an issue. Now, let's consider this. A critical supply chain with a single point of failure. A Strategic National Stockpile – that was never meant for a national response. I understand the supply chain has mostly recovered, and the stockpile is re-stocking, but we can't allow these issues to impede a future pandemic response.

The tragic loss of life, the devastating impacts on the economy and American workers, and also the destabilizing effect on global stability and security, has taken a toll on all of us and all nations. Given the extent of existing issues within the public health system I just discussed, it is little surprise that the initial pandemic response was chaotic and unorganized.

Again, Mr. Chairman, I appreciate the non-partisan nature of this review so far, and I stress the importance of identifying a bipartisan way forward. We've got to figure out how to come together, learn from these lessons, and be better prepared next time. I thank our witnesses for being here today. I look forward to hearing from them and I look forward to hearing their thoughts on the way forward."

**Prepared Testimony of Nicole Lurie, MD, MSPH before the U.S. Senate Committee on  
Homeland Security and Governmental Affairs, April 14, 2021**

Good morning. I am Dr. Nicole Lurie. I currently serve as strategic advisor and response lead at the Coalition for Epidemic Preparedness Innovations, an international organization focused on vaccine development to prevent epidemics and pandemics. From 2009-2017, I served as Assistant Secretary for Preparedness and Response at the US Department of Health and Human Services. In addition to preparedness activities, I was involved with responses to H1N1, MERS, Ebola and Zika outbreaks, as well as other crises that required a whole of government response. I testify here in my own capacity, representing only myself, and not the organization in which I currently work.

We have long known that a pandemic was not a matter of if, but when. Over the past thirty years, our country has made substantial investments to develop robust authorities, plans, and systems to respond in the face of contagion rapidly and nimbly. Yet, ongoing preparedness program funding cuts, and failures of leadership along with active dismantling of preparedness infrastructure by the Trump administration thwarted our ability to build on the institutional knowledge gained during the 2009 H1N1 pandemic, and to rapidly and fully leverage these investments and lessons to protect the American people when confronted with COVID-19.

I start with the premise that the role of government is to protect its people from harms, and to build resilience to those that cannot be prevented. That, by definition, involves preparing for the worst, and scaling back if the worst does not materialize. In the decades leading up to the Trump administration, that was also the posture of the US government, spanning both Republican and Democratic administrations.

**What did US preparedness look like at the beginning of the COVID-19 pandemic?**

Pandemic planning has been a focus in US government dating back to the 1990's. Initially, the nation's focus was largely on influenza, which remains one of our greatest pandemic risks. The Bush administration made significant contributions to preparedness when H5N1, a novel influenza virus, presented a pandemic threat. Since then, there has been substantial progress

preparing for a pandemic across federal, state, and local levels of government and in the private sector. As a country, we have developed, exercised and refined plans, created robust authorities that have enabled federal engagement in both preparedness and response, and developed nimble response systems and infrastructure. These efforts were put to the test during real-life experience with epidemics spanning the Bush and Obama administrations as well as the 2009 H1N1 pandemic, in which the Obama administration embraced and built on the pandemic preparedness investments of the Bush administration.

While none had close to the impact of COVID-19, they provided important experience and lessons, and resulted in institutional learning and iterative improvements in planning. Undoubtedly, the strength of these plans contributed to our country's success mitigating widespread domestic impacts from these events, as well as successful management, prior to 2017, of additional crises necessitating White House leadership and a whole of government response. All were successfully managed within existing authorities.

In the years leading up to COVID-19, certain federal preparedness and response capabilities were maintained and even bolstered. For example, CDC regularly exercised aspects of pandemic planning. In the year before COVID, HHS conducted a long-planned 9-month, whole of government country-level exercise regarding how to respond to a pandemic. While gaps were of course uncovered, they could be anticipated, and there was sufficient basis to know what needed to be addressed and what to expect in the event of a pandemic.

It is also well known that in response to the 2014-5 Ebola epidemic, the Obama administration reconstituted the pandemic office at the National Security Council, and that office developed a comprehensive playbook for pandemic response. The Pandemic and All Hazards Preparedness Act, PAHPA, and its subsequent reauthorizations (PAHPRA and PAHPAIA) provided broad authorities for action, improving our nations preparedness posture with each iteration. And while not a federal initiative, the Johns Hopkins Center for Biosecurity hosted a highly visible exercise in October 2019, attended by many US government officials. The exercise focused on a hypothetical, uncontrolled outbreak of a novel coronavirus (including supply chain

implications), providing practice for multiple federal officials just 2 ½ months prior to the real one starting.

The US also has decades of experience with countermeasure development, especially for influenza vaccines. Each time a novel influenza virus is detected, a risk assessment is performed to determine how far into the vaccine development process to go. This decision reflects an assessment by government experts of whether the virus is likely to be easily transmissible and its impact should such transmission occur. Sometimes it is appropriate to stop after just making a virus seed, and sometimes development goes all the way to stockpiling bulk vaccine. Until recently, countermeasure development was guided through the formal coordination process by the Public Health Emergency Medical Countermeasure Enterprise, which encompassed the major agencies with a stake in the development of countermeasures. This process was remarkably successful, leading the licensure, approval or clearance of over 50 vaccines, therapeutics or diagnostics against recognized public health threats. While it is always our hope that there will never be a need to use the countermeasures we develop, these efforts taught us the value of coordinated investment. Countermeasure development for H1N1 and Ebola also reinforced the value of starting early. We can always take an off ramp if things turn out not to be so bad—but we can't ever make up for lost time. And even off ramps leave you better prepared for the next time.

Unfortunately, a series of actions over the period leading up to the pandemic left us less ready than we otherwise might have been. Among them were the dismantling of the pandemic office at the NSC, and the degradation of the PHEMCE process, which would have been critical to an early start on countermeasures. Another example is a contract for a high-speed mask production line that was terminated without an obvious replacement. Sustaining funding for preparedness has proved challenging across all administrations. For example, from its peak in 2002, the Hospital Preparedness Program alone experienced a 50% decline over a 16-year period. The public health preparedness system tenuously persists with repeated cycles of panic and neglect, hamstringing efforts to build durable capabilities, not least a high quality, sustainable workforce. But even these actions cannot fully explain the failure of the Trump administration to act early in the pandemic. Our withdrawal from the world stage

compromised important strategic global health relationships; nonetheless, there was sufficient warning of a potential pandemic by the last week in December 2019, to warrant attention, and by mid- January, when cases were detected outside of China, the threat was very clear.

Of grave concern to me, in key federal agencies where a more assertive and robust response was needed, the approach appeared to be one of decision-making governed principally by political considerations. In addition, I believe that a climate of fear and retribution that had developed over the few years leading up to the pandemic inhibited seasoned, usually apolitical, career employees in key agencies from stepping up and speaking out about problems with the response.

All of that said, this would have been a difficult situation for anyone to manage, and the adage that even the best of plans does not survive first contact with the enemy is true. But in this case, it does not appear that the enemy—in this case, the virus-- was even acknowledged, or that a plan was activated to fight it. In other words, we lost valuable time, both time between when this virus was first noted as a likely threat in late December 2019, and the interval between the first case in the US on Jan 21, 2020, and the declaration of the public health emergency at the end of January. Other than important, early NIAID efforts to jumpstart the Moderna vaccine, for which they should be applauded, it wasn't until much later that countermeasure development started in earnest and at scale. And even when the pandemic was finally acknowledged, there was no overall plan forthcoming from the Trump administration.

Much has been made about whether or not the 'authorities' that enable the federal government to contribute to response were sufficient. These include those authorities provided for under the Public Health Service Act, which allows for the declaration of a public health emergency with HHS in charge, as well as the Stafford Act, which allows for the declaration of an emergency or major disaster with FEMA in the lead. I contend that there were sufficient authorities to act and to execute a robust, whole of government response. I say this because these authorities were exercised and proved sufficient during the 2009 H1N1 pandemic, in dealing with Ebola and other crises. There was, however, a failure to leverage the full power

that these authorities provide such a response; in short, all the authorities in the world cannot make up for the failure of leadership. The failure to fully engage and deploy the deep experience and expertise of the federal government and provide urgently needed national leadership, early and consistently, has resulted in untold numbers of deaths and chronic health problems for many who survived COVID, let alone the mental health consequences for so many-health care workers, parents, children, and those who have lost loved ones to this pandemic.

Recognizing that the retrospectoscope is a powerful instrument, here are 10 things that should have happened early on:

- 1) **Immediately acknowledging an infectious disease threat anywhere is a threat everywhere, convening a whole of government effort to examine the scenarios of how COVID-19 could unfold, making a plan for each.** This could have included defining situational triggers for when Stafford Act authorities to coordinate a whole of government domestic response should have been invoked.
- 2) **Communicating, from the top, in a clear, forthright and consistent way about the severity of the threat and need for an all-hands-on-deck response.** We all know that did not happen, and that the inconsistent communication, rampant epidemic of 'truth decay' and politicization of the response confused the public, with deadly consequences.
- 3) **Developing and executing a real time research agenda for dealing with the unknowns of COVID-19.** This had been a practice in past crises. While the WHO activated its R&D Blueprint to guide the global research response in February, no such coordinated effort appeared to guide a domestic research response or U.S. federal research investments. This led to delays, and lack of focus and coordination, in fully leveraging the vast capabilities of the U.S. intramural and extramural research enterprise.

- 4) **Strengthening surveillance and testing.** The US had warnings that the SARS-CoV-2 virus was coming before it arrived, and thankfully, astute clinicians, as well as travelers from China, alerted us to early cases. We were dealing with a new disease, with high levels of asymptomatic transmission, but relying on traditional methods of surveillance and contact tracing that required widespread availability of diagnostics. The failure of test development at CDC, coupled with the legacy of disinvestment in public health meant that neither local public health departments nor their public health labs were equipped to handle volume of required testing or contact tracing; rapid development and scaling of diagnostics, validation of diagnostic tests and laboratories to perform them, including rapid execution of partnerships to facilitate expanded testing and tracing early on, would have been in order. BARDA authorities for countermeasure development could well have been leveraged early to this end to develop and scale additional test capacity. As we know, that did not happen. Further, even in the face of electronic record companies' unprecedented collaboration to provide data, public health and health care data remained largely unlinked and underleveraged. Both for surveillance purposes, and for managing healthcare aspects of the pandemic, this has remained a huge shortcoming.
- 5) **Examining what resources were on hand, including what was in the Strategic National Stockpile (SNS) and determining what would be needed.** It should have been clear in the first weeks of January that there were not enough masks and PPE in the SNS, and it would have been sensible to make provisions to manage what was there and conserve its use. Emergency contracts to ramp up production of these products and to gain visibility into the supply chain were urgently needed but did not materialize. Instead, we shipped masks overseas. Without a doubt, the failure to provide adequate PPE for healthcare workers resulted in needless infections and deaths and traumatized a vital workforce. It is now estimated that 3600 healthcare workers died on the front line in the United States. It is noteworthy that severe shortages of PPE were a feature of H1N1 and Ebola epidemics; in each case, HHS was able to put together a system to gain

visibility into what was in the supply chain without compromising business relationships, supporting voluntary reallocation of resources that were double- and triple-ordered.

- 6) **Recognizing the rest of health-related supply chain vulnerabilities and scaling up US production where needed.** Given our dependence on offshore manufacturing of so many key health, medical and laboratory products, it would have been critical to catalog those likely to be in short supply, including essential medicines and laboratory testing equipment, and do everything possible to maintain adequate inventories. This was not done, despite knowing that these kinds of shortages, from antibiotics down to testing wells and pipette tips, had been noted in previous exercises and should not have been a surprise. Our nation's entire critical supply chain management system needs a major upgrade, including for health products.
- 7) **Preparing the healthcare system.** Failure to recognize the pandemic seriously at the outset meant the healthcare system was not put on alert; it lost valuable time in preparing for the enormous patient surge, in terms of staffing, equipment and supplies, policies and procedures, and coordination across communities. In the face of inadequate funding for the Hospital Preparedness Program, it was no surprise that regional healthcare coordination entities struggled with patient load balancing and distribution for as long as they did. Further, this was a new disease, and early on, HHS failed to provide an adequate mechanism to connect clinicians to one another to recognize new clinical syndromes, share treatment experiences and rapidly study promising practices.
- 8) **Starting countermeasure development early, as soon as the threat was detected, to include diagnostics, therapeutics and vaccines.** Fortunately, as part of its prototype pathogen approach, NIAID had been working on stabilizing the coronavirus spike protein and on developing mRNA vaccines for several years, and the Institute took critical early steps to advance this work. But BARDA was hamstrung in taking early action to develop

countermeasures, both because of the lack of a standing emerging infectious disease fund and because of administration decisions not to reprogram funds to get started. It was not until March that an emergency supplemental provided a bolus of funds for this purpose. Ultimately, Operation Warp Speed, with its funding and leadership came together and has had remarkable achievements in the vaccine development arena. But they couldn't make up for lost time either, especially with regard to diagnostics and effective therapeutics. As a point of reference, CEPI was concerned enough about the potential for a pandemic that its staff called developers working on MERS vaccines and other platform technologies even before the sequence was posted and asked them to pivot work to a new vaccine. CEPI resources pale in comparison to those of the US government; I would posit that we would be in a different place the USG had made a resource commitment and mounted a Warp Speed-like effort much earlier. You can always take an off ramp. You can't make up for lost time. A standing emerging infectious disease fund that can be used to start countermeasure development in the face of a new threat is urgently needed. Emergency supplementals simply take too long.

- 9) **Coordinating and providing guidance for state, local and tribal governments and health care settings.** While we live in a federalist system, we also recognize that in a public health emergency people expect to be treated similarly regardless of where they live. Big differences in policy across states or regions also confuse the public and put confidence at risk. Further, many jurisdictions don't have the expertise or resources to develop comprehensive guidance, based on best available evidence. State, local, tribal and territorial (SLTT) governments and their healthcare systems should not have been left to fend for themselves, or to have to compete with one another for scarce resources, driving up their prices. The federal government works best in strong partnership with SLTT government and their healthcare entities; this did not happen.

- 10) **Mobilizing private sector partners.** Private sector entities of many kinds were eager and willing to step up, and there were multiple missed opportunities to consider what was needed, and to leverage and coordinate their resources, making more rational use of what existed in a fragile supply chain. Instead, multiple, poorly thought contracts, such as those for more ventilators, were executed seemingly ad hoc, often wasting taxpayer funding without producing needed products.

#### **Looking forward**

While this pandemic is far from over, it's now time to look forward, and to envision the kind of system we want for the future. This hearing provides a welcomed opportunity to move that process forward. In doing so, it is critical to remember that a good response does not happen automatically but is built on the back of strong day to day systems. I know many on this committee would like to focus on new authorities, and while some will undoubtedly be helpful, I do not believe new authorities will solve our basic problem. They simply can't substitute for leadership. Here are some of the things we need to do.

- 1) **Make it safer for career employees to do their jobs, including maintaining the integrity of our science agencies.** There is not an easy answer here, and the issue deserves considerable thought before jumping into a solution. There are lessons to be learned from near miss reporting at places like the FAA, other confidential, non-whistleblower reporting systems, and outside, independent monitoring entities. Understanding that some aspects of government are inherently political, we need to protect those components that should not be. Preparedness and response has traditionally been a bipartisan effort; we cannot let political interference and partisan division take our country down.
- 2) **Reconceptualize the organization and role for public health.** This is not a time to build back public health to the time of days gone by, but to reconceptualize it, including getting more clarity and focus on the most critical roles for CDC and its relationship to state/local health agencies; how they are organized and funded, how they gather,

analyze and report data; and how we can achieve the nation-wide ability to link and leverage public health and healthcare data while maintaining individuals' privacy and confidentiality. This will require modernizing the science and laboratory systems available to public health agencies to ensure they have the tools to act and sustainable funding to do so. It's been gratifying to see the recent down payment on next-generation genome sequencing at CDC. It will also require new surge-ready public-private partnerships with commercial and academic labs, and other kinds of workforces, and novel ways of funding public health that are results-driven. We can no longer expect public health agencies to live off the funding fumes of the last emergency.

- 3) **Create and maintain a standing emerging infectious disease fund at BARDA that can be activated when a threatening new disease shows up.** The cost of preparedness means paying to lean forward, because you can't make up for lost time. The sooner diagnostics are available, the sooner you can manage an outbreak. The sooner vaccines are available, the sooner you can prevent a pandemic. And, the sooner therapeutics are available, the sooner you can treat those who become ill. All of these save lives.
  
- 4) **Re-examine the SNS.** It's time to take a hard look at what the SNS is for; right now its budget is dominated by maintaining important countermeasures for bioterror threats like anthrax. While those are critically important, it crowds out other important aspects of readiness, like a supply of masks to bridge to surge manufacturing. That bridge to surge production needs to be ready for activation 'on demand'. Additionally, I believe the SNS needs to be able to monitor critical supply chains, and to maintain and procure critical health and medical material, domestically sourced to the extent possible. This includes not only essential medicines, but raw materials. The shortages of raw materials for making diagnostics, masks, vaccines and the like must not happen again.

- 5) **Strengthen and clarify FDA authorities.** There are a set of important issues around FDA authorities that need examination, including what should constitute criteria for an emergency use authorization, what a strong vaccine safety monitoring capability needs to encompass in the setting of widespread emergency use, aspects of clinical trial authorization, and how diagnostic test and labs are authorized. Recognizing that these are the jurisdiction of other committees, I mention them here for completeness only.
- 6) **Protect against cyber-threats.** While not referenced in my enumeration above, it is important to recognize that our research, our manufacturing, our supply chains are subject to near constant cyber-attacks by both state and non-state actors, and our public is subject to considerable misinformation from similar sources, contributing to the epidemic of truth decay. While dramatically increased in tempo, there was not a sufficiently aggressive posture toward these threats. Fortunately, the Biden administration has begun to address this, but more is likely needed.

Finally, remember that **preparedness requires continuous, proactive financial investment.** On “blue sky” days, it’s easy to think that this isn’t a priority, that the things we’ve already purchased or the systems we built are sufficient, and that precious resources may be better spent elsewhere. It is definitively not the case that you can build and buy ‘stuff’ and then you are done. Technology gets out of date, and people, our most precious resource, come and go. Some of our agencies face such stiff competition from the private sector that they cannot attract and retain the caliber of people needed to respond. Staff need to be trained, need to practice and need to be in day-to-day jobs that can provide critical surge when the situation demands it. Response depends on strong day to day systems, and those need to be built, incentivized and maintained. It seems that the public, and Congress as their voice and instrument, all too easily lose sight of the fact that preparedness is forever. We cannot afford to let our guard down. Too much is at stake. Almost 600,000 dead, and still counting.... I look forward to seeing our nation act on the hard lessons learned.

**TESTIMONY OF DR. JULIE L. GERBERDING**  
**Before the United States Senate Committee on Homeland Security & Governmental Affairs**  
**“Preparedness for COVID-19: The Initial Pandemic Response and Lessons Learned”**  
**April 14, 2021**

Chairman Peters, Ranking Member Portman, and other members of the Committee, thank you for the opportunity to appear today. Americans and people around the world are still coping with the SARS-CoV-2 pandemic and its tragic consequences. Unfortunately, we cannot expect this pandemic to be an isolated event and must take steps now to improve our overall preparedness and response capabilities. Reviewing, and more importantly, acting in response to the lessons we have learned so far are essential steps toward strengthening our health security as well as our broader national and global security. Thank you for your leadership in this critical area.

Supported by Congress and several Administrations since 2000, significant progress has been made in increasing our nation’s pandemic preparedness. However, our performance in the context of the current pandemic is far from optimal and reveals many persistent vulnerabilities across the public-private continuum that we must address. A crisis as far reaching as the COVID-19 pandemic merits a comprehensive evaluation, at least as extensive as the 911 Commission report that followed the terrorist attacks in 2001. However, we are still in the midst of the pandemic, and need to apply what we have learned until now to better protect lives and help restore socioeconomic stability for Americans – and people around the world.

The doctrine that frames our national pandemic response includes four main phases: (1) rapid detection of the threat at its source; (2) rapid containment of the outbreak at its source; (3) failing that, mitigation of the consequences of the threat wherever it appears; and finally, (4) recovery. There will be many lessons to be learned from our performance in each of these phases, but since we are currently still in the mitigation phase, I will focus today’s testimony on a few of the most critical requirements and lessons learned in this phase of the pandemic.

I base these observations and recommendations on my work with the Center for Strategic International Studies (CSIS) Commission on Strengthening America’s Health Security that I co-chair with former Senator Kelly Ayotte, my tenure directing the CDC from 2002-2009 that encompassed several global health threats including SARS and avian influenza outbreaks, and my experience as president of the vaccine business and other executive leadership responsibilities in the private sector at Merck & Co., Inc. I believe that the lessons from the pandemic present the perfect opportunity to course correct, even as we are still navigating its ongoing effects.

#### **LESSONS LEARNED AND POTENTIAL ACTIONS**

##### **Early Detection and Response**

Detecting people who are infected before they can transmit infection to others is the starting point in any outbreak response. Case detection allows isolation of those who pose a risk and quarantine of their contacts who may be incubating infection. In addition, case detection helps pinpoint “hotspots” where outbreak investigations and other special studies should be conducted

to understand the dynamics and determinants of transmission. SARS-CoV-2 proved to be a very challenging pathogen in this regard, since such a large proportion of infectious people were asymptomatic and unknowingly transmitted the virus.

A **critical requirement for success** is rapid and widespread availability of reliable testing for infection. Unfortunately, the early SARS-CoV-2 virus tests distributed across our country were limited in number, unreliable, and restricted to symptomatic people with travel risk factors or their close contacts, factors that impaired the early phases of the public health response. Scale is also proving to be a challenge as new variants of virus emerge and population-based information about the clinical, epidemiologic, and immunologic impact of these emerging genetic lineages is becoming essential to ongoing mitigation planning.

Perhaps the most important of the many **lessons learned** from this experience are: (1) the CDC, FDA, public health laboratories, private sector diagnostic companies, and academic institutions must collaborate in the development of rapid, reliable, and scalable diagnostic testing platforms, and also plan and exercise their deployment and updating; (2) existing regulatory policies made early collaborations challenging; (3) the state and local public health workforce is severely hampered by inadequate human and financial resources to provide testing, trace contacts, and implement immunization programs at the scale required for success. Unfortunately, prevention in public health is seldom prioritized when resources are limited.

**Specific actions to address these issues include:**

1. Create sustainable funding models, not just emergency supplemental funding, that support our public health infrastructure and workforce to achieve a more proactive model rather than a reactive model of preparedness;
2. Ensure adequate funding of prevention and immunization infrastructure in our health system more broadly since this pandemic clearly demonstrates these are critical for health protection as well as for national and economic security;
3. Accelerate data system modernization as a key public health system enabler. Easy access to interoperable, real-time data can transform the local, state, and national public health infrastructure and response capability as we know it;
4. Incentivize, develop, standardize, and deploy digital tools and other approaches to augment traditional “shoe leather” approaches to contact tracing and related public health interventions.

**Provide Safe, Quality Care to Ill People**

Some of the most **critical requirements for success** in this priority area include the physical space and related equipment to support a surge in demand for hospital care (and especially intensive care), a robust supply chain of medicines, supplies, devices, and equipment, the environmental controls and personal protective equipment to protect the entire health care workforce, and methods to sustain non-hospital and home care for COVID-19 as well as unrelated primary care and other essential medical services.

The overarching **lesson learned** from our experience so far is that our health care system must

achieve a level of preparedness commensurate with the scale of the threats we anticipate and the vulnerabilities of the communities served, and this will require significantly greater financial, physical, and human capital resources than we had previously achieved. Substantial investments in supply chain strengthening, stockpiling of essential medicines, vaccines, and equipment, and contingency surge capacity are also key. COVID-19 has also once again taught us the painful lesson that the most vulnerable people in a pandemic are those who sustain the greatest degree of socioeconomic and health disparity at baseline. Though this lesson should have been learned during prior outbreaks and natural disasters, we have sustained little progress in addressing the needs of our hardest-hit communities.

**Specific actions to address these issues include:**

1. Prioritize virus testing and vaccines for people in the most vulnerable communities;
2. Enhance access and linkages to primary care medical services, cancer screening, perinatal care, routine vaccinations, mental health services, substance use services, and dental care, especially among people in hard-to-reach communities and environments;
3. Conduct a thorough medical supply chain assessment to understand and address vulnerabilities;
4. Examine how to best strengthen the Strategic National Stockpile performance to be the most effective and efficient during a pandemic (e.g., consider expansion of personal productive equipment, ventilators, and other durable medical equipment);
5. Augment supplies of antibiotics, intravenous fluids, and other medicines to sustain critical care;
6. Formalize augmented health care workforce contingency plans (credentials across states, retirees, volunteers, Department of Defense) and update training;
7. Create an interoperable pandemic health data network (instead of local and state stand-alone networks);
8. Engage and incentivize the private sector in planning efforts;
9. Exercise and improve planning with accountability from partners to follow through on lessons learned.

**Slow Transmission in Communities**

Personal protective equipment, hand and environmental hygiene, and social distancing in all its forms remain **critical requirements** for preventing infection. The pandemic experience is highly variable around the world, but some countries like New Zealand and several others in Asia have had remarkable success in using these approaches to mitigate the pandemic's impact – even before vaccines became available.

Important **lessons learned** from this variability across countries and regions are numerous, but the most salient include: (1) consistent and trustworthy leadership communication matters in achieving high degrees of cooperation and compliance; (2) self-quarantine and other forms of social distancing are very effective, but can cause tremendous economic, community, family, and personal disruption, and are difficult to sustain (especially without economic support for those

who cannot work or lose employment); (3) misinformation and intentional disinformation are dangerous threats, especially when polarized in complex political environments; 4) evolving science and updated guidelines and requirements often confuse the public and further erode trust.

**Specific actions to address these issues include:**

1. Sustain financial support to offset the economic and other hardships imposed by social distancing requirements;
2. Provide communication support to trusted community leaders who can translate government and other expert advice to constituents;
3. Assess federal authorities and other regulatory and legislative strategies to determine how better coordination and harmonization of guidelines and requirements across states might be achieved during a pandemic;
4. Support resource centers and academic research to help understand and combat misinformation and especially disinformation;
5. Encourage more engagement and closer communication between Members of Congress and the CDC and other response agencies so that our leading public health professionals have the unfettered ability to provide the best available science to decision-makers.

**Countermeasure Development and Deployment**

The most **critical requirement** for success is a robust competitive biopharmaceutical sector with pre-existing capacity and agility to innovate, develop, and deploy medicines, diagnostics, and vaccines that address emergent health challenges. In addition, sustainable investments in innovative platform technologies, pre-pandemic development of countermeasures that target known or potential families of threat agents, regulatory innovation, and manufacturing innovation and scale are essential.

That leads me to the biggest **lesson learned** during the pandemic so far – the tremendous value that our entire biopharmaceutical and related ecosystem, including small and large pharmaceutical companies, small biotechnology companies, academic investigators, research institutions, foundations, and patient advocacy organizations, is delivering to our nation and the world. In the context of unprecedented collaboration, speed, and investments, hundreds of innovative vaccines, antiviral and immunologic therapies, and diagnostics are in development, and the largest proportion of these originated in the United States. Ultimately, these are the tools that will end the pandemic.

But another important lesson is that development of these products is complex, expensive, and carries no guarantees; for this reason, we need to support the pursuit of multiple approaches, expect that most will fail, and prepare for an ongoing cycle of updating and improving the products that do emerge. In addition, as with health care system preparedness, we must invest in these capabilities and innovations commensurate with the scale of the threats we anticipate, and that will require significantly greater financial, physical, and human capital resources from governments and investors than we previously planned.

**Specific actions to address these issues include:**

1. Right now, sustain focus on vaccine deployment in the United States and globally as our highest value countermeasure;
2. Increase support for accelerated development and deployment of antiviral and immunologic therapies, especially in light of emerging virus variants;
3. Start now to increase investment in robust countermeasure development, via CEPI, NIH, and the private sector, to address future threats;
4. Accelerate investments in vaccine confidence and community engagement to build trust and, at the same time, counteract misinformation and disinformation at every level;
5. Augment vaccine distribution, delivery, administration, and tracking;
6. Invest in novel strategies to detect counterfeit countermeasures;
7. Assess the need for additional regulatory changes to reduce complexity, sustain safety, and encourage more standardization and harmonization of medicine and vaccine development across jurisdictions.

**LONG-TERM OPPORTUNITIES**

Even while we are in the midst of responding to the current pandemic, we must remain mindful of tomorrow's threats, and that requires a new health security doctrine. In November of 2019 before the SARS-CoV-2 pandemic was apparent, the CSIS Commission on Strengthening America's Health Security outlined several actions that should be taken to enhance our biosecurity. We framed the Commission's output with a simple understanding: health security is national security, in a world that is increasingly dangerous and interdependent. Biological threats – outbreaks from natural, intentional, and accidental causes – are occurring more often and at the same time, the world is increasingly insecure, violent, and disordered. This is exactly the danger zone where biological outbreaks occur, and the current SARS-CoV-2 pandemic is no exception.

Unfortunately, when a health crisis strikes – COVID-19, measles, MERS, Zika, dengue, Ebola, pandemic flu – our policymakers rush to allocate resources in response. Yet all too often, when the crisis fades and public attention subsides, urgency morphs into complacency. Investments dry up, attention shifts, and a false sense of security takes hold. That realization led the Commission to conclude that the U.S. government needs to break the cycle of crisis and complacency and replace it with a doctrine that can improve threat prediction and pre-emption, and enhance detection, containment, mitigation, and recovery. That was true in the pre-pandemic era, and is certainly even more true today.

The United States must establish permanent health security leadership as a central pillar of the National Security Council (NSC), by a credentialed and qualified expert. This is critical to guaranteeing effective oversight of global health security and biodefense policy and spending. As has been reinforced over the last year, public health is an essential component of national security.

We also must achieve greater operational capability to execute in disordered settings around the world. We need to invest directly and consistently, over the next decade, in the capacities of low-income countries. The best approach to protect the American people is to stop outbreaks at their source. The Global Health Security Agenda has a proven track record in building health systems and health security preparedness, and that investment must continue.

With the window of opportunity presented since the onset of the SARS-CoV-2 pandemic, we have the opportunity to strengthen our capabilities and repair the gaps in our public health infrastructure, and hopefully continue towards the path of strengthening our international credibility and biosecurity.

Again, thank you for the opportunity to testify in front of you today, and it is my sincere hope that we can work closely together to advance the U.S. biosecurity agenda, so we are better prepared for the next pandemic.

**Statement of RADM Joseph L. Nimmich (USCG, ret.)**  
**Senate Committee on Homeland Security and Governmental Affairs**  
**Hearing on “Preparedness for COVID-19:**  
**The Initial Pandemic Response and Lessons Learned”**  
**April 14, 2021**

Good Morning Chairman Peters, Ranking Member Portman and members of the Committee. Thank you for the opportunity to appear before you today to share my views on the Nation’s “Preparedness for COVID-19: The Initial Pandemic Response and Lessons Learned.” I am proud to have served as the Deputy Administrator at FEMA from September 2014 to January 2017 and in the U.S. Coast Guard for over 33 years. I hope my experiences can help provide insights into some of your questions surrounding the future preparedness of our Nation and important lessons learned in responding to the ongoing pandemic.

With hindsight being 20/20, I am confident in saying that the United States was not prepared for COVID-19. But the challenges, missteps, and even some of the successes during the early days of the pandemic should not have been a surprise to anyone involved in emergency response at the federal level. HHS ASPR’s “Crimson Contagion” pandemic exercise, run from January to August 2019, identified and predicted almost all of the problems encountered.

Numerous national, state and local, private and public organizations participated in this exercise, which was conducted to test the capacity of the federal government plus 12 states to respond to a severe influenza pandemic. The similarities between the exercise findings and the shortcomings realized in the real-life COVID-19 response events are striking, but likely came too late to change the outcomes predicted.

The Crimson Contagion report is one of four primary sources which have informed my current views on the federal response to this pandemic to date. The other three include:

- First-hand, non-attributable conversations with FEMA leaders directly involved in the COVID-19 response.
- FEMA’s COVID-19 Initial Assessment Report from January 2021. This report highlights the extraordinary actions FEMA has undertaken to support the Nation throughout this crisis, and details a number of Key Findings and Recommendations which I believe will be critical to delivering effective support during future disasters.
- The work of the *Commission on the National Response Enterprise* convened by Business Executives for National Security. I was honored to serve as one of the Commissioners for this effort, along with a very august team of leaders, including Senators Hassan and Cassidy.

I draw on the Commission’s work heavily for my testimony today. Two things make this study second to none on this topic, in my opinion. First is the breadth of knowledge of the BENS Commissioners and Working Group members – drawn from business, civil society and

government at all levels – which brought a true “whole of society” approach to this challenge. This, combined with hundreds of interviews of current and past federal, state, and local emergency response officials and experts and focused research on the topics of Surge, Supply, People, Roles, and Infrastructure & Economy, resulted in recommendations that are both actionable and critically needed. I commend to the Committee the Commission’s final “*Call to Action*” report which offers 11 recommendations for redesigning our response capabilities to embrace 21st Century realities. The report can be found at:  
<https://www.bens.org/file/national-response-enterprise/CNRE-Report-February-2021.pdf>.

Let’s start with the good news: The Commission strongly believes that the components of an integrated national response capability are largely in place. COVID-19 demonstrated, however, that execution challenges remain across the board, particularly when a crisis impacts numerous states simultaneously and extends over a prolonged period. Today I want to focus on weaknesses in two areas highlighted in the *Call to Action* – the surge of human and materiel resources and the critical need for planning and exercising:

**Plans and Exercise:** It is not because of a lack of planning for disasters that performance often falls short of expectations. It is more about the nature of current planning itself which is problematic. A plan is never as good as when it is first developed -- explicit coordination and communication channels exist and stakeholders are all aware of their specific roles; complete information needed to make decisions is available and all participants have a transparent common operating picture; and all options for possible action to address the event have been identified and laid out.

Time then passes -- the plan sits (often for years); new crises deflect decisionmakers’ attention; and people and positions change. The trust among stakeholders dissipates and the plan loses its currency and effectiveness. Or facts on the ground during an event do not align exactly with the plan that was tested. In either scenario, everyone is left at the start of an actual event trying to relearn and execute a response plan. As Administrator Craig Fugate taught me, all too often “we plan for what we can do, not what we have to do.”

Two clear examples: Back in the spring of 2005, a hurricane exercise was held in New Orleans testing the plans for a Category 5 storm impacting New Orleans. Failure of the levy system was never even considered. Only a few months later, Hurricane Katrina hit causing more than 50 failures of the levees and flood walls. In the winter of 2010, I oversaw the bi-annual Spill of National Significance exercise off the coast of Portland, Maine. The scenario was predictable – an oil tanker running aground with a known quantity oil spilled. Then that April came the Deepwater Horizon oil spill with continuous oil flow from an underwater well, which created one of the largest environmental disasters in American history.

We continue to plan for the known and not the improbable, when as history has shown us, the improbable will almost certainly occur. And all plans without frequent and regular exercises are just shelf ornaments. No one has time to read and review plans once a crisis has begun. It is

only through regular exercises that plans become alive, can be updated and improved, and stakeholders are able to develop and maintain relationships which build trust.

The Commission identified several specific weaknesses in FEMA's existing National Exercise Program that negatively impact our response capabilities in general and which were contributing factors to performance challenges early on in the COVID response. These include (but are not limited to) the exercises' low frequency, limited participant knowledge of the National Response Framework and supporting crisis-specific response plans, and reported delegation of responsibility for exercise participation from senior leaders to subordinates. The Commission recommends creating or redesignating a leadership position within the Department of Homeland Security to oversee the development and operation of a comprehensive National Crisis Response Exercise Framework to more effectively coordinate testing and exercising of plans across the emergency response enterprise.

An intangible but critical benefit of the frequent exercising of response plans which is often overlooked is the trust it builds between key stakeholders. The breakdown in trust between individual states, between states and the federal government, between business and government, and between American citizens and all of the above, played out every night on t.v. with regard to everything from the need to quarantine and wear facemasks to shortages of ventilators, PPE, Clorox wipes and toilet paper. The Commission rightly points out in its *Call to Action* that, "While trust cannot be legislated or mandated, it emerges naturally from regular interaction, shared experiences, and personal relationship-building. Emergency response leaders and their teams should make every effort to continually build and deepen trusting relationships among all stakeholders within and across sectors and to establish confidence in plans, systems, and providers through continual testing and exercising."

**Surge:** A second area of weakness in the Nation's response enterprise exposed by COVID-19 is our ability to surge critical human and material resources when needed, but this was definitely not the first time.

The ongoing need to surge to disaster sites FEMA personnel who are responsible for the day-to-day running of the agency has severely limited FEMA's ability to modernize. During the 2017 hurricane season for example, three Category 4 hurricanes made landfall in the US and its territories at the same time some of the deadliest wildfires in history were burning on the West Coast. Over 80 percent of the FEMA workforce was deployed to help address these immediate needs. But these FEMA employees have day jobs -- they oversee programs supporting individuals and states; they run the National Flood Insurance program; they run billions of dollars in grant programs; they work to build national resilience; they hire and support the FEMA workforce, and the list goes on. Today the number of FEMA personnel deployed in support of national vaccination efforts matches the 2017 level.

Primary responsibility for responding to crises properly resides in states and localities. But the ever-increasing number of declared emergencies and disasters, not to mention nationwide events such as the pandemic, will continue to put unsustainable pressure on FEMA personnel,

their jobs, and the Agency's ability to manage improvements through technology and policy. The Nation needs a well-trained workforce which can be called up during national emergencies to deliver assistance to areas where it is needed.

I am particularly passionate about one of two recommendations the BENS Commission makes to help alleviate this extraordinary pressure on FEMA personnel -- the creation of a Civilian Expertise Reserve program to recruit civilians with targeted skill sets that can deploy when required. These CERs would provide emergency managers with a highly trained, rapid-response force of professionals who can augment or supplement existing resources. The Commission believes that the National Guard provides a useful model for forming a CER and its operating authorities.

Individual CERs could activate for service in both state and federal crises. Guard best practices for recruiting (such as tuition assistance and stipends), and employment protections (covered by the Uniformed Services Employment and Reemployment Rights Act) could apply to CERs as well. Similarly, aspects of FEMA's Disaster Reservist, Surge Capacity Force and Community Emergency Response Team (CERT) programs may offer useful insights on how to streamline time commitment requirements, recognizing that CERs will need to take into account training and skills already resident within certain professions. The National Guard's command and control structure could also present a model for designing the CER management and leadership systems. CERs would have state-based operations and a leadership hierarchy in each state, with national leadership based in Washington, D.C., which would assume command upon federalization.

Contemporary emergency response demands new kinds of skill and expertise, including advanced data analytics, cybersecurity, and information technology, which join more traditional specialized skill sets such as medicine, electrical engineering, and construction. The Commission recommends piloting two CER programs, directed at recruiting medical personnel and cybersecurity professionals. Insights, lessons learned, and best practices would inform the launch of additional CERs. As envisioned, the Civilian Expertise Reserve program would provide the Nation with a trained surge workforce who have exercised together regularly, built trust in each other and plans, to address disasters large and small, local, state or federal, while delivering that essential capacity only when need.

In addition to human capital, our national ability to deliver materials and commodities during a national crisis were shown during the pandemic to be inadequate as well. It is important to understand that resilience cost money. The ability for a nation to be resilient while always striving to be maximally efficient usually run counter to each other. We see this most clearly in the decision about whether to stockpile commodities or to have adequate production capability in reserve.

The response to COVID-19 required both the drawing on national stockpiles AND new production and one thing became abundantly clear -- the ability to accurately understand true need for and availability of critical goods and services in order to facilitate equitable allocation

requires the sharing of extensive, dependable, real-time data. The BENS Commission strongly advocates for both the redesign of FEMA's National Response Coordination Center (NRCC) and the creation of a FEMA Surge Center to develop this ability for use during future disasters. Several lines from the *Call to Action* convey key components of these organizations for your consideration:

“Command and control for surge should reside within FEMA, coordinating with the Departments of Homeland Security, Defense, Treasury, Energy, Transportation, Health & Human Services, and others, as appropriate. IT capabilities within each agency and department must be capable of integration to enable real-time communication; and need cloud-capabilities to facilitate data sharing, analytics, and guidelines. Creating a FEMA surge hub would maximize the efficiency of planning, communicating, and executing surge response and fortify industrial base resilience writ large. Improved visibility into real-time data analytics will drive more effective response. Other technologies such as AI can also provide better situational awareness of supply and demand to drive decision-making in real-time. As the federal government invests in new IT capabilities and retires legacy systems, the ability to quickly communicate with private and civil sector stakeholders will improve significantly. With improved information sharing, relevant data will be visible across sectors, most notably around roles and responsibilities and current gaps and capabilities.”

In closing, COVID-19 has shown us that there are many achievable changes to our national response programs and processes which can make our Nation more resilient in the face of future crises, both natural and human-made. But there is one thing which cannot be improved upon, and that is the dedication of every first responder and every FEMA employee who answers the call when America needs them.

For the first time in U.S. history every state and territory received a Federal Disaster Declaration during this pandemic. The NRCC has been activated for over 390 days, exceeding the record of 70 days in 2017 more than five times over. The Nation calls on FEMA every day across many missions, both traditional and unique, and the dedicated FEMA workforce answers the call every single time. Congress needs to better understand what is being asked of FEMA, provide the necessary authorities, and adequately resource FEMA for success.

Thank you again for your time today and I am happy to answer the Committee's questions.

## U.S. Senate Committee on Homeland Security and Government Affairs

***Preparedness for COVID-19: The Initial Pandemic Response and Lessons Learned***  
April 14, 2021

**Written Statement by:**  
**Elizabeth A. Zimmerman**  
**Former Associate Administrator**  
**FEMA Office of Response and Recovery, 2014-2017**

Chairman Peters, Ranking Member Portman, and Members of the Committee, thank you for the opportunity to speak with you today regarding the *Preparedness for COVID-19: The Initial Pandemic Response and Lessons Learned*. My name is Elizabeth Zimmerman. I am the former Associate Administrator for the Federal Emergency Management Agency's (FEMA) Office of Response and Recovery (ORR), serving in that role from 2014 – 2017 and as the ORR Deputy Associate Administrator from 2009-2014. I've been an emergency manager for over 35 years at both the state and federal levels and remain actively involved in emergency management since leaving FEMA.

The opinions expressed are my own.

The COVID-19 Pandemic is a *maximum of maximum* event that stressed and challenged the United States' health, social, and economic systems. For the first time in our Nation's history, all 50 states, the District of Columbia, and the U.S. territories are under a state of emergency and granted Presidential declarations at the same time because the consequences of COVID-19 were so severe that the state, local, tribal and territorial (SLTTs) governments were overwhelmed.

The last major disaster with a majority of the country involved in simultaneous response was during Hurricane Katrina when most of the states received and supported evacuees from Louisiana. COVID-19 differs in that every SLTT government was responding and focused on saving the lives of their residents, while attempting to prevent the collapse of their economy and medical systems. SLTT governments were competing for the same scarce resources, such as medical personnel, personal protective equipment (PPE) and ventilators, while simultaneously attempting to prepare for the unknowns of the COVID-19 global Pandemic.

There were several issues that arose in the early days of COVID-19 that in hindsight could have been handled more effective and efficiently. As a nation, and as emergency response and public health systems, we must learn from our mistakes. Now is the time to take action and develop effective and efficient plans and procedures and better define authorities to be ready for the next pandemic, or any event that could impact us as COVID-19 has done.

During this testimony, I outline six areas that I believe require further exploration as we gather lessons learned and implement change. For each area, I provide some background, the issues or concerns associated with that area, and then recommendations for future action.

### The Plans

The goal of preparedness and planning activities and their coordination is to ensure better response outcomes during incidents.

Federal and SLTT governments and the private sector must work together now to develop a national pandemic plan and approach for unity of effort, unity of command, and unity of delivering scarce resources. This plan must be trained, exercised, analyzed for lessons learned, and once established be maintained with repeated training and exercising to be ready for the next event. This pandemic plan must be national in scope with the assumption that jurisdictions are overwhelmed and unable to assist each other, just as we have seen during COVID-19.

In researching disaster response plans to refresh my memory for this hearing, I found several detailed plans that were publicly available and saw mention of plans and directives that were not publicly available. The time spent searching for these plans and directives was frustrating for an experienced emergency manager and I imagine the lack of publicly available directives makes incidents like COVID-19 even more confusing for SLTT end users to know which response plan is the guiding document.

The National Response Framework (NRF) is the known national foundational framework for all incident responses and is designed to be scalable and agile for all supporting plans to fall under. Following the Anthrax attacks in 2001, the federal government invested a lot of money on processes and plans centered on public health response – bioterrorism and pandemics in particular. Communities developed anthrax and smallpox response. One of the latest plans, January 2017, is the Biological Incident Annex (BIA) to the Response and Recovery Federal Interagency Operational Plans (FIOPs). The BIA is the *federal* organizing framework for responding and recovering from a range of biological threats, including pandemics.

However, it was not publicly seen that these plans were being used during the on-set of COVID-19 nor does it seem that there was a national COVID-19 response plan.

Also, there was a 2018 Pandemic Crisis Action Plan (PanCAP) that was customized for COVID-19 specifically and adopted in March 2020 by HHS and FEMA; the plan identified the U.S. Department of Health and Human Services (HHS) as the Lead Federal Agency (LFA) with FEMA supporting for coordination. However, a mere five days after the national COVID-19 emergency was announced, FEMA became the LFA.

Issues:

The established federal plans were not publicly referenced, used or coordinated with stakeholders during the COVID-19 event. No national level plan was developed and shared with SLTT governments and/or the private sector. Everyone was left to their own response. Many of the SLTT governments had developed public health emergency plans following the 2001 anthrax attacks. These plans were refreshed or SLTT governments created new pandemic plans following H1N1 and Ebola. It is unknown if the SLTT governments adapted and utilized these plans specific for COVID-19 that included medical countermeasures (MCMs) points of dispensing operations. Despite Operation Warp Speed being publicly touted, it does not appear that the federal government nor SLTT governments invested in vaccination planning prior to the Emergency Use Authorization (EUA) of the COVID-19 vaccines being granted.

The bottom line is that too many potential plans and also the lack of national strategic plan created confusion across stakeholders.

Recommendations:

There needs to be a strategic review and updating of national-level as well as SLTT-level public health emergency plans. These plans need to be streamlined, coordinated, exercised and remain as living documents, revised from lessons learned as incidents occur as to not become stagnant or forgotten. If not revised, then there are only lessons experienced and not learned.

In national level events, there needs to be one national plan that is socialized with stakeholders at all levels for their review and input, that is then adopted and exercised on blue sky days and implemented during the crisis creating a coordinated outcome.

Plans must be developed in coordination with the operational needs of the entire response team. No one should plan in a vacuum, isolated from the response, that takes place at the local level.

Lead Federal Agency

HHS has statutory authority for health and medical events, to include the Health and Human Services Secretary signing a National Public Health Emergency for COVID-19 in January 2020. The PanCAP adopted March 2020, identifies HHS as the Lead Federal Agency (LFA), and HHS is also the designated lead for the NRF's Emergency Support Function (ESF) #8 - Public Health and Medical Services. Soon after the PanCAP adoption in March 2020, FEMA was asked to take lead for the COVID-19 response and operations. FEMA immediately consolidated HHS's operations into FEMA's National Response Coordination Center (NRCC). While it is smart to rework a plan when needed, one must question if the PanCAP was ever exercised, since within five days of the COVID-19 unified response kicking off, the PanCAP was changed to name FEMA as the LFA.

Issues:

HHS does not have the structure to quickly respond to events. Based on my prior experience and observations, HHS's components are internally stove piped and do not coordinate well. COVID-19 is not the first time FEMA has been called upon to organize and/or lead events that are HHS's core responsibility. From H1N1, Ebola, and Zika, to the Flint Water Crisis and the surge in Unaccompanied Minor Children, FEMA was directed to coordinate and lead despite it being HHS's mission and authority.

One of FEMA's missions during Ebola was to deploy an Incident Management Assistance Team (IMAT) to the U.S. Centers for Disease Control (CDC) to organize, support and coordinate their operations center. During the Unaccompanied Minor Children emergency at the Southwest Border in 2015, FEMA coordinated HHS's Administration for Children and Families (ACF) Leadership Group to convene other federal government agencies to assist in finding accommodations for these children within the proscribed 72-hour timeframe under the Flores decision.

At that time, HHS leadership noted that they did not have the authority to mission assign other federal agencies (OFAs) nor did they have funding to support these types of events.

Many times, during national crises, FEMA becomes the federal government's 9-1-1. In addition to supporting HHS in the incidents noted above, FEMA has been called upon to exercise its authority in support of other federal agencies outside of Stafford Act events. For example, FEMA was intimately involved in the Environmental Protection Agency and U.S. Coast Guard's Deep Water Horizon response, the Department of Agriculture's Avian Flu response, and the U.S. Housing and Urban Development's long-term recovery and housing mission. FEMA has, and will always quickly respond should the President request that the Agency exercise its expertise to lead OFA's events, but it is must be noted that a successful response is likelier to occur when FEMA is brought in at the front of the emergency rather than late in the game. In addition, while FEMA has successfully exercised its authority in response to OFA's events, if FEMA is going to be the 9-1-1 for the federal government, they should be given the authority, staffing and resources to ensure their success.

Recommendations:

A decision must be made to determine who is the lead for the unity of effort in events that fall outside of the Stafford Act, such as pandemics. Clear, strong leadership is required for national level events with a direct connection to the White House.

If HHS is going to be the lead agency for all health and medical events, their defining statutes should be revised with clear authority granted to lead, mission assign OFAs, and be funded and staffed at the appropriate level for these events.

All agencies with a LFA authority should be mandated and funded to train and maintain full staffing to ensure they can perform the duties required to lead disaster operations, no matter the type of disaster. Agencies also need to have the urgency and operations tempo for quick response. FEMA has this in their DNA.

#### **Data Management/Models/Forecasting**

The plans mentioned earlier are high level frameworks; they do not detail the information required for situational awareness. Decision-makers need data and information to help them see trends and to formulate mitigation strategies. Good data is necessary for evidence-based decision making and is key in critical response operations when lives are at stake. During the COVID-19 pandemic, gathering reliable and timely data from SLTT governments proved to be very difficult.

#### **Issues:**

It took days, weeks to get vital data from the private and public hospitals, manufacturing companies, and U.S. Government stockpiles as well as global counterparts. There was no system in place ahead of COVID-19 to determine the necessary data points for true situational awareness. Information was not forthcoming nor quickly shared.

There were no pre-event standardized data points established for what information would be needed to successfully model and forecast a COVID-19 type event, e.g., commodities in storage (federal, private sector), use-rates on commodities, re-supply (time frame), total number of hospital beds and available beds, other hospital supplies.

Hospitals and hospital systems are often reluctant to share data to prevent their competitors from knowing their operating status and business practices. Federal attempts to collect hospital data were challenging.

Different federal and private industry systems were used to gather COVID-19 hospitalization data, and these systems experienced difficulties with hospital participation, obtaining accurate data, and sharing data across platforms. At least initially, there was no one centralized data collection agency for the reporting.

Without comprehensive data sets, many COVID-19 models were developed with fragments of data, using algorithms to fill in blanks and not always accurately doing so. Universities or other entities became the source of COVID-19 case forecasting models versus HHS or CDC.

#### **Recommendations:**

In the future, a systematic approach is required to ensure a better, synchronized gathering and sharing of data, particularly hospitalization data, for outbreaks and public health threats. The

information technology infrastructure, data protocols and standards, and any necessary Memorandum of Understanding (MOU) must be developed now to prepare for the next public health threat.

We should be taking lessons learned from historic events to plan better data management for future events. On a blue-sky day, we should be establishing the specific data points and sources of information necessary for forecasting and modeling to enable better situational awareness and evidence-based decision making. We should use lessons learned from past events to model the number of deaths, injuries, property losses, etc. against what happened and what could have been mitigated with interventions. Define what the outcome was versus how the outcome could have been improved with mitigation strategies.

The National Security Council should determine the agency that should lead data collection for what events, working with the National Institute for Standards and Technology (NIST) to create data standards. For all events involving critical infrastructure, the Cybersecurity & Infrastructure Security Agency (CISA) could play a vital role to coordinate with the 16 Critical Infrastructure Sectors to establish the data collection requirements. CISA serves as the NRF's ESF #14 – Cross-Sector Business and Infrastructure Coordinator and Primary Agency, and they seamlessly work each day with the private sector to share information.

Also, the private sector should be engaged early on in the discussion, planning and coordination. They are an integral part of the team. For public health events, HHS should pre-establish agreements with the medical and health industry to share data during events.

FEMA also has an example for private sector inclusion – the National Business Emergency Operations Center (NBEOC). There are hundreds of private sector companies registered to participate and coordinate with the NBEOC. CISA also has established frameworks in place through sector-specific Information Sharing and Analysis Centers (ISACs).

### Commodities/Logistics

National level emergencies require a strong, coordinated, and unified logistics system with an agile distribution system. The purchasing and storage of commodities is cumbersome, requiring a unity of effort and precision prior to shipping to distribution points. HHS's Strategic National Stockpile (SNS) is not designed to support a national, global pandemic. It is a buffer for smaller contained events.

### Issues:

The SNS warehousing, and distribution system is not agile. The process is cumbersome at best. Commodities had to be unpacked, counted, expiration dates verified, and repacked before they could be shipped to state and local distribution points.

Just-in-time logistic does not work in nationwide, global events. Manufacturing cannot keep up with urgent unplanned demands, or even regular supply chains when manufacturing locations are critically impacted by an event. We saw this during COVID-19 and as recently as the 2011 earthquake in Japan.

There was no unity of effort for the purchasing of commodities during the COVID-19 pandemic.

Recommendations:

HHS should review the SNS for the intended use of the commodities that are required for pandemics and other events, the shipping process, and the international supply chain for re-stocking. HHS and the federal government should be using best practices to modernize the SNS, looking at efficient and effective private-sector models, e.g., Walmart, Amazon.

The federal government, in coordination with stakeholders, must determine what the minimum supply is needed for a stockpile, and work with the private sector to determine necessary production ramp up. Specifically for medical supplies where mass warehouse quantities do not exist, there should be established partnerships with the manufacturers to determine the minimum supply needed on hand and have them manage the supply to keep commodities rotated and current in inventory.

Agencies need to develop strong partnerships with private sector companies to build a robust U.S. supply chain plan.

The federal government should investigate and consider one unified purchasing system in national level incidents to avoid competing for the scarce resources and to ensure the resources get to where they are needed the most, when they are needed.

Going forward, resilience must be built into the whole of government logistics and supply chain.

Funding

In the end, everything always comes down to who, how and when the funds are available in emergencies and disaster events, especially for COVID-19.

Similar to natural weather disasters, the SLTT governments' tax base was decimated with the closure of businesses and individuals quarantined. Along with the unprecedented number of COVID-19 disaster declarations, many SLTTs are on the brink of financial ruin and looking for funding streams to reimburse their unanticipated costs. Successful response and recovery operations often comes down to who, how and when the funds are available in emergencies and disaster events, especially for COVID-19.

Issues:

COVID-19 had a multitude of federal funding mechanisms. HHS funds, FEMA Disaster Relief Fund (DRF), other existing grants or programs repurposed to assist as well as supplemental Congressional appropriations, e.g., the CARES Act and American Rescue Plan Act. These funds are much appreciated and needed by the SLTTs although they are not easily accessed. There is no one-stop-shop for federal funds.

Duplication of benefits is a high risk for many applicants based on the variety of funding sources. Some applicants may have submitted claims for the same costs to multiple agencies, in hopes one of them would reimburse them. It is contingent upon the applicant to track all of their funds to re-pay any duplicates.

Recommendations:

The federal government should consider one overarching funding framework that is outcome focused. The framework needs a lead agency; needs simplicity and flexibility; and for funds to be quickly disbursed. There was confusion as several of the funding options could be used for the same expenses and many federal agencies were slow to develop guidance or issued interim guidance that was later changed leaving SLTT governments frustrated by the process.

The federal government should take the lessons learned from COVID-19 and build the structure and policies now ahead of the next event.

The CARES Act, Department of Treasury's Coronavirus Relief Fund (CRF) funds appear to be a good example for ease of access and use for the end user. The CRS funds provided the applicants with the flexibility to use the funds as they best saw fit, with minimal requirements.

Workforce

HHS has over 70,000 employees and FEMA has more than 20,000 employees.

Typically, this time of year, FEMA's workforce will have some down time among responding to tornados, severe storms and river flooding; however, that is not the case in 2021. FEMA's workforce is stretched thin and focused on missions outside of their core responsibility – COVID-19 and the recent surge in unaccompanied minor children.

Issues:

FEMA's workforce is stretched thin with climate change and the resultant increase in natural disasters, and now they are focusing on missions outside of their core responsibility.

The majority of FEMA's workforce are on-call, temporary workers that support Stafford Act events.

Recommendations:

If FEMA is going to be the 9-1-1 for the federal government, they should be given the authority, staffing and resources to be successful.

The FEMA Reservist Program needs to be professionalized, similar to the military reserve corps, where individuals can take a leave of absence from their jobs to serve their country and have the guarantee of returning to their job. Currently, FEMA's Reservist Program consists of individuals who are retired, at the beginning their career, or risk not having a job when their assignment is over. There is little incentive for individuals to be reservists, which causes higher rates of staff turnover.

FEMA needs to be focused on hurricane season preparation, using the time to coordinate and exercise with the SLTTs and other federal agencies. Hurricane season is fast approaching with another year of a high number of hurricanes predicted, and it is important to remember that it only takes one bad hurricane to impact the nation and resources will be stretched even thinner. Currently, FEMA's number of deployed staff is the second highest on record only to the 2017 hurricane season – Harvey, Irma and Maria – and they expect to top this number of deployed staff in early May. In addition, FEMA's resources have seen cuts, for example, the FEMA Corps program went from over 1,000 participants to 150 in the last four years.

Conclusion

While it is important to move deliberately and quickly to resolve issues that arose during the COVID-19 pandemic, we need to be careful not to be hasty in our reaction. Before overhauling federal, state, local, tribal and territorial response powers and capabilities, all governments should take a comprehensive review of what is necessary to meet emergencies. For example, before creating new legislative mandates that limit the ability for emergency responders and other officials to effectively meet the challenge of new events, there needs to be an analysis of both the problem and what might be the unintended consequences of proposed solutions.

In conclusion, thank you for the opportunity to participate in this hearing on *Preparedness for COVID-19: Initial Pandemic Response and Lessons Learned*. As a lifetime emergency manager, it is important for us as a country to include the whole community (e.g., federal, state, local, territory, tribal, private sector, non-governmental entities) in preparing for, mitigating against, responding to, and recovering from all events. We need to be prepared and planning for the next pandemic, **NOW**, as COVID-19 demonstrated it's the proverbial not if rather when it will happen. We must take action now to ensure better outcomes in the future.

**Post-Hearing Questions for the Record  
Submitted to The Honorable Nicole Lurie, MD  
From Senator Gary Peters**

**“Preparedness for COVID-19: The Initial Pandemic Response and Lessons Learned”  
Wednesday, April 14, 2021**

1. The 2019 Crimson Contagion tabletop exercise issued preliminary findings just months before the COVID-19 pandemic, warning of inadequate funding, a lack of clarity on federal interagency roles, and insufficient domestic production capacity for critical countermeasures, like PPE.
  - a. To your knowledge, did the Trump Administration implement any of the Crimson Contagion recommendations? *I am not aware that any recommendations were implemented.*
  - b. What is your assessment of how those findings could have improved the COVID-19 response? *Findings could have been used to improve coordination, funding speed and flexibility, release of Stafford Act funds, communication with states, supply chain challenges, etc. All of those (and more) would have resulted in significant mitigation and likely have saved lives. In addition, work done before the exercise, particularly with regard to a system to identify and redeploy unobligated funds, could have been used to jumpstart countermeasure development. All actions would have required acknowledgement of a pandemic.*
2. The U.S. has previously responded to a number of public health threats, including SARS, H1N1, and Ebola. What lessons are universal to public health threats, and what can we do to ensure effective solutions are actually implemented?  
*Universal lessons-1) surveillance is essential 2) plan for all scenarios once a threat appears on the horizon-best to lean forward and pull back rather than lean forward 3) importance of clear, consistent communication 4) start countermeasure development asap (including diagnostics) 5) engage private sector partners early 6) prepared hospital system 7) impossible to manage a crisis without good situational awareness/data-HHS and CDC data systems need to be in the modern era, link healthcare and public health, and be close to real time 8) you can get away with disinvesting in public health for a year or 2, but then the disinvestment comes back to bite you very badly. To ensure effective solutions are implemented, Congress should a) provide adequate funding b) insist on an annual report on progress in implementation c) require annual or biannual exercises aiming at measuring progress in implementation.*
3. Private sector engagement has been critical during the COVID-19 response, particularly in scaling up testing, as well as the development and distribution of medical countermeasures. How can we better engage the private sector early in a public health crisis for diagnostic testing and medical countermeasure development and distribution?

*With regard to diagnostic tests, BARDA could put in place advance contracts with test developers to enable them to begin test development early on; BARDA also should have an emerging infectious disease fund to jumpstart countermeasure development. It should be recognized that there are times that development should start but will need to be terminated if the treat turns out not to be so severe. Additionally, private sector suppliers need to collaborate on a supply chain and logistics operations center to keep supply chains open, especially for prioritized products.*

4. A significant misconception is that the vaccines we currently have for COVID-19 were suddenly developed when the pandemic hit last year. COVID-19 vaccines such as the Pfizer and Moderna mRNA vaccines are the result of longstanding federal investments in science. How can we improve upon our public/private partnerships so that we are ahead of the next emergency, whatever that might be? *Indeed, the mRNA vaccines were the result of more than a decade of investment by NIH and BARDA, and we continue to need to develop the ideal set of platforms that can be used to rapidly make vaccines against any emerging pathogen. We need to invest in new platforms, and make vaccines against prototype pathogens that can be rapidly adapted to new pathogens. This will also help clarify the regulatory pathways for the approval of 'pathogen' changes on these platforms, once we become confident in these platforms*
  
5. Our nation's emergency management and public health systems have both served a critical role in the COVID-19 response. How can we better integrate our nation's emergency management and public health systems, both federally and at the state and local levels, for both preparedness and response efforts?

*Public health needs to view emergency response as a key function, and have sustainable funding at federal state and local levels to fulfill management of public health emergencies. Bidirectional collaboration at all levels, between emergencies, can be used to ensure the entities know one another, plan together, exercise together. Data systems that integrate data streams across sectors and provide shared situational awareness to all parties will go a long way. Finally, triggers for escalation of management from a public health led event to unified command or coordination by emergency managers should be developed, practiced, and widely understood. A bi/nonpartisan roster of emergency management and public health professionals with experience in successfully managing public health crises could be deployed to review department plans, observe and evaluate exercises, and advise in real time those confront with emergencies.*

**Post-Hearing Questions for the Record  
Submitted to Dr. Nicole Lurie  
From Senator Josh Hawley**

**“Preparedness for COVID-19: The Initial Pandemic Response and Lessons Learned”  
April 14, 2021**

- 1) In your written testimony you stated that, during the Trump administration, “our withdrawal from the world stage compromised important strategic global health relationships.” Speaking of global health, do you think that the World Health Organization has been a model institution during the COVID-19 pandemic?

*Almost all institutions have misstepped during the COVID-19 pandemic and certainly WHO’s communication and decisionmaking could have been faster and clearer. Strengthening WHO, and clarifying its mission, roles and responsibilities must become a priority.*

- 2) One recommendation you do not mention in your written testimony is travel restrictions. In general, what is your view of travel restrictions as a mitigation tool? Was former President Trump right to cut off travel from regions in China as he did at the beginning of the pandemic?

*Travel restrictions remain a controversial mitigation tool. They can be used to buy time. By the time former President Trump cut off travel from regions in China, it was too late, and the restrictions were very poorly executed. Sadly, we did not use any time we bought to plan an effective response.*

**Post-Hearing Questions for the Record  
From Senator Gary Peters  
Dr. Julie L. Gerberding Response  
May 27, 2021**

**“Preparedness for COVID-19: The Initial Pandemic Response and Lessons Learned”  
Wednesday, April 14, 2021**

1. What impact did political pressure at the CDC and elsewhere have on ensuring the American public got sound and scientifically based guidance and what needs to change to make sure this doesn't happen again?

Since I was not an employee of the CDC during this time period, I am unable to answer this question.

2. During the COVID-19 vaccine roll-out, we saw a primary focus on temperature monitoring of the bulk vaccine shipments to the states. As vaccines rolled out, there were numerous accounts of vaccine wastage due to temperature issues in sub-distributing and handling of vaccines. As a lesson-learned, what types of methods could be used to ensure vaccines are shipped at the proper temperatures both domestically and internationally?

Ensuring the safe and equitable distribution of vaccines is critical to ensuring that individuals are protected from infectious diseases. Under non-disruptive circumstances, this process is exceedingly complex, requiring hundreds of steps and thousands of complex tests, all validated to ensure that every single vial has the identical, high quality and safety. This requires skilled human resources, as well as cross-sectoral collaboration with a range of partners, including governments, multilateral organizations, non-governmental organizations, and commercial organizations.

Major threats, like a global pandemic, complicate these processes and underscore the need for public health preparedness and response capabilities to be commensurate with the scale of anticipated threats and the vulnerabilities of communities. When vaccines are developed during an emergency such as a pandemic, safety, quality, efficacy, and development speed are the primary objectives. Other characteristics, such as thermostability, product image, and shelf life may not be optimized in the first generation of products. Therefore, the down-stream supply networks need to anticipate these needs and build agility into their preparedness to safely and rapidly deploy these medical counter measures.

To prepare for future emergencies, I would recommend the following actions be taken to ensure seamless distribution of these critical countermeasures:

- Conduct a thorough assessment of down-stream supply chain capabilities to identify vulnerabilities, and make subsequent investments in supply chain strengthening and contingency surge capacity;

- Enhance vaccine distribution, delivery, administration, and tracking, including through the use of electronic tracking, to monitor the vaccine throughout the distribution system and allow states to plan accordingly;
  - Improve demand planning and reallocation/redistribution capabilities to ensure ample supply is delivered in a timely manner to the most critical and at-risk areas; and
  - Develop best practices for fulfillment of orders of needed supplies throughout this period in ways consistent with both antitrust and crisis standards.
3. The 2019 Crimson Contagion tabletop exercise issued preliminary findings just months before the COVID-19 pandemic, warning of inadequate funding, a lack of clarity on federal interagency roles, and insufficient domestic production capacity for critical countermeasures, like PPE.
- a. To your knowledge, did the Trump Administration implement any of the Crimson Contagion recommendations?
  - b. What is your assessment of how those findings could have improved the COVID-19 response?

Findings from the Crimson Contagion along with real-world insight and lessons learned that have been gained from the COVID-19 pandemic can help inform the federal government's response to future pandemic threats.

Preliminary findings of the report emphasized the importance of sufficient federal funding sources to support pandemic response at the state and local level. Proactively establishing dedicated and sustained funding streams to support ongoing disease surveillance and the development and maintenance of infrastructure to support medical countermeasure deployment can help ensure that local, state, and federal stakeholders are well positioned to rapidly respond to future pandemic threats.

The preliminary findings also emphasized the importance of standardized information management systems across federal and state agencies. To that end, investments should be made now to enhance surveillance systems to identify and monitor disease outbreaks and improve immunization information system capabilities to aid countermeasure response and deployment in the future.

Lastly, the report identified a lack of clarity regarding interagency roles during pandemic response. This presents an opportunity for the federal government, as a coordinating body, to more clearly articulate roles and responsibilities between agencies for information dissemination to the public. Federal agencies play critical roles in emergency preparedness and response and it is essential that the agencies closely communicate and collaborate, to ensure consistent and coordinated efforts to provide timely, equitable, and effective deployment, distribution, dispensing, and administration of medical countermeasures in an emergency.

4. The U.S. has previously responded to a number of public health threats, including SARS, H1N1, and Ebola. What lessons are universal to public health threats, and what can we do to ensure effective solutions are actually implemented?

Health security is national security, in a world that is increasingly dangerous and interdependent. Biological threats – outbreaks from natural, intentional, and accidental causes – are occurring more often and at the same time, the world is increasingly insecure, violent, and disordered. This is exactly the danger zone where biological outbreaks occur, and the current SARS-CoV-2 pandemic is no exception.

Unfortunately, when a health crisis strikes – COVID-19, measles, MERS, Zika, dengue, Ebola, pandemic flu – our policymakers rush to allocate resources in response. Yet all too often, when the crisis fades and public attention subsides, urgency morphs into complacency. Investments dry up, attention shifts, and a false sense of security takes hold. That realization led the CSIS Commission on Strengthening America’s Health Security to conclude that the U.S. government needs to break the cycle of crisis and complacency and replace it with a doctrine that can improve threat prediction and pre-emption, and enhance detection, containment, mitigation, and recovery. That was true in the pre-pandemic era and is certainly even more true today.

The SARS-CoV-2 pandemic has only served to highlight the vulnerabilities in our system that need to be addressed now and for the future. Pandemic preparedness requires a new health security doctrine. I would recommend the federal government focus on the following areas to advance preparedness and response efforts for this pandemic and for what I believe are the inevitable future pandemics we will face:

- Establish permanent leadership at the National Security Council to guarantee effective oversight of global health security and biodefense policy and spending;
- Establish a clear and sustained national preparedness health security doctrine and strategy;
- Create an immediate and long-term financing mechanism to properly execute the health security strategy and assure ongoing preparedness capacity-building in the United States, including front-line public health and health care facility preparedness and a fit-for-purpose Strategic National Stockpile (SNS);
- Ensure that the SNS mission and budget are in full alignment with the national health security strategy and that lines of responsibility and authority regarding control of the stockpile, and the precise chain of command for its use – from the federal level to the state and local public health and health care entities that will utilize its assets – is clearly articulated;
- Augment CDC’s capability to combat disinformation and promote better communications that are science-based, including providing clear and coordinated communication with the American public about the emerging evidence and evolving guidelines for this virus;
- Fully engage the private sector in planning and executing the national health security strategy; and
- Invest to accelerate development of countermeasures to address known threats and new platforms and manufacturing innovations to prepare for new and emerging threats.

5. Private sector engagement has been critical during the COVID-19 response, particularly in scaling up testing, as well as the development and distribution of medical countermeasures. How can we better engage the private sector early in a public health crisis for diagnostic testing and medical countermeasure development and distribution?

In the context of unprecedented collaboration, speed, and investments, hundreds of medical countermeasures have been developed and are in development. Ultimately, these countermeasures will help end the current pandemic and prepare us for future threats. The development of medical countermeasures is complex and resource intensive over many years, and carries high rates of failure; because of this, we must invest in diverse medical countermeasures commensurate with the scope and scale of the current threats we face as well as future threats that we have not yet seen. This will require an agile approach, along with sustained and sufficient financial, physical, and human capital resources from governments and investors both in the U.S. and around the world to create a more robust insurance policy for future global health security. Ensuring that distribution networks are robust and capable to deal with a diversity of threats is also paramount, yet this has not received the same level of investment and attention as have development efforts. The following steps could be taken to accomplish these goals:

- Increase support for accelerated development and deployment of antiviral and immunologic therapies, especially in light of emerging virus variants;
- Assess the need for regulatory changes to reduce complexity, sustain safety, and encourage more standardization and harmonization for medicine and vaccine development;
- Foster harmonization and simplification of post-approval regulatory requirements, including manufacturing process changes and importation testing across jurisdictions;
- Ensure early and consistent communication across the federal government (including the Food and Drug Administration and the Centers for Disease Control and Prevention) and with private sector partners;
- Identify and provide support for the end-to-end supply chain that will be needed for development, production, and deployment efforts and strengthen supply chain security; and
- Understand and address the potential impacts of COVID-19 production on critical non COVID-19 products.

Our entire biopharmaceutical and related ecosystem, including small and large pharmaceutical companies, small biotechnology companies, academic research institutions, and patient advocacy organization, bring tremendous value to our preparedness and response efforts. Our companies are leaving no stone unturned. Continued support and partnership in countermeasure development will be key.

6. A significant misconception is that the vaccines we currently have for COVID-19 were suddenly developed when the pandemic hit last year. COVID-19 vaccines such as the Pfizer and Moderna mRNA vaccines are the result of longstanding federal investments in science. How can we improve upon our public/private partnerships so that we are ahead of the next emergency, whatever that might be?

The COVID-19 vaccine programs have been enabled by pre-investment in vaccine platform processes that allowed existing pre-clinical safety and manufacturing knowledge to be leveraged for rapid construction of vaccine candidates with antigens selected through the emerging scientific understanding of SARS-CoV-2. In addition, the establishment of effective public-private partnerships based on complementary capabilities and aligned goals have encouraged access to critical reagents and knowledge sharing that has furthered the development of critical research tools such as animal models and laboratory tests. Frequent and expedient engagement with regulatory agencies, resulting in rapid alignment on endpoint definitions and laboratory testing standards, are expected to decrease the cycle time for protocol planning while assuring that the different vaccine candidates undergo consistent, stringent scientific assessments.

Through cooperative efforts, many vaccine programs have proceeded at unprecedented speed while still assuring rigorous safety and efficacy testing. Cooperative aligned efforts will be needed in the future to ensure successful vaccines will reach the public. For example, innovative regulatory review processes and global regulatory agency harmonization that acknowledge the importance of equitable access and the dependence of vaccines on global supply chains will be required for broad approval around the globe. These and additional steps are critical to allow for broad access while preserving healthy market dynamics that drive incremental, value-added improvements to vaccine product characteristics, as well as investments toward increased capability to address future infectious disease risks.

The development of future vaccines against currently known as well as unforeseen infectious threats will benefit greatly through continued investments in vaccine technologies that can be rapidly applied to new problems, further strengthening of collaborative partnerships, and enhanced regulatory science and alignment between countries.

7. Our nation's emergency management and public health systems have both served a critical role in the COVID-19 response. How can we better integrate our nation's emergency management and public health systems, both federally and at the state and local levels, for both preparedness and response efforts?

The current pandemic reminds us that infectious diseases know no borders and that coordinated planning and response by our emergency management and public health systems from the global to local level is critical to protecting against threats. The pandemic also illuminated some of the barriers to effective coordination globally, at every level of government within the U.S., and with private sector partners – from our global tracking and surveillance efforts and regulatory policies at the federal level to a lack of a robustly staffed and resourced state and local public health workforce.

First, it is important to examine the critical partnerships formed throughout the pandemic, including partnerships between and among the Centers for Disease Control and Prevention, the Federal Emergency Management Agency, the Department of Defense, and public health officials across the globe and at the state and local levels. Some of these partnerships originated under urgent and acute conditions. Documenting and reinforcing new models of cooperation will help streamline preparedness and response efforts in the future. In addition, responsibilities and legal

authorities for federal, state, and local officials must be clearly delineated. This can help accelerate response efforts, avoid delays in action due to lack of clarity, and reduce public confusion.

Investing in robust data systems is also key. Strengthening our global disease surveillance systems that can track and identify disease outbreaks and building, enhancing, and sustaining systems that aid countermeasure response and deployment are essential. These systems are the foundation for improved threat assessments and situational awareness for officials at every level of government and abroad, as well as for domestic and international non-governmental entities.

Bolstering regional disease response capabilities can help triage treatment needs. Ensuring that trauma centers, health care facilities, emergency medical services, and others can communicate about capacity and supply – needs and excess – can help ensure that providers can adequately respond to any public health threat. Alternative sites of care and service delivery must also be clearly identified, and there must be plans in place to transform sites, as needed. This includes a range of service delivery sites – from those designated as treatment facilities to those best situated to be alternative vaccination sites. To support these sites, personnel readiness is key.

**Post-Hearing Questions for the Record  
From Senator Josh Hawley  
Dr. Julie L. Gerberding Response  
May 27, 2021**

**“Preparedness for COVID-19: The Initial Pandemic Response and Lessons Learned”  
April 14, 2021**

- 1) We’ve heard some Biden administration officials tell us that once you are fully vaccinated from COVID-19, you still need to wear a mask. Given your experience as a former Director of the CDC, what is your view on this? Doesn’t telling Americans that they still need to wear a mask and stand six feet apart after being inoculated work to further increase vaccine hesitancy?

Throughout the pandemic, personal protective equipment, hand and environmental hygiene, and social distancing in all its forms have been critical requirements for preventing infection. However, we know that these measures can also cause tremendous economic, community, family, and personal disruption, and are difficult to sustain. It is important to find the right evidence-based balance between sufficient social distancing, including masks and avoidance of crowds, with prudent steps to resume business activities and more normal activities of daily life. This is imperative. We are now seeing this evolve rapidly – as more people become vaccinated, the need for these other interventions is reduced.

We also agree that vaccine confidence is a serious concern that must be addressed. We need to build trust in the new vaccines and address escalating levels of misinformation. We are dismayed by the ongoing dissemination of information that is inaccurate and/or misguided. We have also seen the erosion of trust in governments and the health care workers who are conducting vaccination programs. Ultimately, this misinformation threatens a dangerous reduction in people choosing to receive vaccines, which could extend the duration of the pandemic.

The federal government has an important role to play in increasing the confidence that the public, especially underserved communities, has in COVID-19 vaccines. A clear and coordinated national strategy to understand and address vaccine hesitancy is a critical component of ensuring uptake of COVID-19 vaccination in underserved and vaccine hesitant communities. Working alongside partners, the federal government can help increase vaccine confidence through health-literate communications, public awareness campaigns, health care provider empowerment, and media engagement to ensure timely, clear, culturally sensitive, and accurate information is reaching all Americans.

**Post-Hearing Questions for the Record  
Submitted to The Honorable Joseph Nimmich  
From Senator Gary Peters**

**“Preparedness for COVID-19: The Initial Pandemic Response and Lessons Learned”  
Wednesday, April 14, 2021**

1. Our nation’s emergency management and public health systems have both served a critical role in the COVID-19 response. How can we better integrate our nation’s emergency management and public health systems, both federally and at the state and local levels, for both preparedness and response efforts?

**The witness failed to respond to these questions at time of printing. If responses are received, they will be on file in the committee offices for public inspection.**

**Post-Hearing Questions for the Record  
Submitted to Elizabeth A. Zimmerman  
From Senator Gary Peters**

**“Preparedness for COVID-19: The Initial Pandemic Response and Lessons Learned”  
Wednesday, April 14, 2021**

1. Our nation’s emergency management and public health systems have both served a critical role in the COVID-19 response. How can we better integrate our nation’s emergency management and public health systems, both federally and at the state and local levels, for both preparedness and response efforts?

The first recommendation to better integrate our nation’s emergency management and public health systems is to embed key staff from HHS, Office of the Assistant Secretary for Preparedness and Response (ASPR) into FEMA at the Headquarter and Regional Offices to work on a daily basis. They must be fully committed to be there and have the authority to make decisions and take actions on behalf of HHS leadership. The key positions could include planners, logistics, response operators and any other position as required to enhance the mission. This must be a team of individuals; it will take more than one individual to accomplish the mission. This concept is not new, several agencies (DoD, NWS, USCG, USACE and others) have Liaison Officers (LNOs) assigned fulltime to work at FEMA Headquarters and in the Regional Offices.

The next recommendation is to include HHS staff on the FEMA Integration Teams (FIT). FEMA has embedded the FITs into many state’s emergency management offices working daily side by side with the state staff. The goal is to have a FIT in every state and territory office. The benefit of these teams is they know and understand the state or territory they are working in and serve as the first-hand resource to them. They also, provide the connectivity back to the Regional Office and when disasters happen, they are there to immediately support. No time is wasted on identifying and transporting people into the state or territory. The FIT could be expanded to include members from public health. These members could be the conduit to the state and territory public health offices to complete the integration.

One more option for establishing a more unified, comprehensive system for a more integrated emergency management and public health system is to transfer the HHS, Office of the Assistant Secretary for Preparedness and Response (ASPR) to FEMA. This move could integrate the key elements (authorities, roles, responsibilities, funding, staffing, SNS, etc) for preparedness and response into one agency.

Another option is to engage FEMA’s National Advisory Council (NAC). It consists of members from across the SLTT and in multiple disciplines including health. The NAC could be charged to look at this issue and develop recommends for a national integrated organizational structure framework.

Thank you for the opportunity to provide comments and recommendations on this very important issue. We as a nation must be prepared and have a cohesive response in place before the next public health event.



**COVID-19 PART II:  
EVALUATING THE MEDICAL SUPPLY CHAIN  
AND PANDEMIC RESPONSE GAPS**

**WEDNESDAY, MAY 19, 2021**

U.S. SENATE,  
COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL  
AFFAIRS,  
*Washington, DC.*

The Committee met, pursuant to notice, at 2:30 p.m., via Webex and in room SD-342, Dirksen Senate Office Building, Hon. Gary C. Peters, Chairman of the Committee, presiding.

Present: Senators Peters, Hassan, Sinema, Rosen, Ossoff, Portman, Johnson, Lankford, Scott, and Hawley.

**OPENING STATEMENT OF CHAIRMAN PETERS<sup>1</sup>**

Chairman PETERS. The Committee will come to order.

Today's hearing, the second in a series examining the Federal Government's response to the coronavirus disease (COVID) pandemic, will focus on vulnerabilities in our medical supply chain that were fully exposed last year, as the United States struggled to secure desperately needed supplies to combat the spread of COVID-19.

Despite years of warnings about the dangers of our Nation's overreliance on foreign sources and manufacturers for critical medical supplies, our Nation was still unprepared to acquire the masks, the gloves, the gowns, and ventilators necessary to treat the significant number of COVID patients, stop the spread of the virus, and save lives.

While the Federal Government had plans in place and authorities available to help address these longstanding supply chain challenges, the Trump administration failed to use them at the onset of the pandemic to coordinate an effective, unified Federal response.

To date, this tragic and historic public health crisis has taken the lives of more than 586,000 Americans, left untold economic destruction in its wake, and resulted in long-term health consequences for thousands of Americans.

Thanks to the ingenuity of American scientists and the Biden administration's actions to ensure rapid distribution of vaccines, there is light at the end of the tunnel.

However, as we learned in our first oversight hearing, the loss of life, the damage to the health and livelihoods of countless Ameri-

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<sup>1</sup>The prepared statement of Senator Peters appear in the Appendix on page 119.

cans, and the suffering caused by this pandemic were not inevitable.

Swift, decisive action, and a comprehensive national strategy from the previous administration could have reduced the devastation this pandemic wrought on our communities.

The Federal Government should have taken early action to ramp up production of personal protective equipment (PPE) and other critical medical supplies by issuing emergency contracts or fully invoking the Defense Production Act (DPA).

Instead, the Trump administration left individual States to secure supplies and combat the virus on their own. Instead of a coordinated Federal effort to secure and direct supplies where they were needed the most, the Trump administration's inaction forced States, and even individual hospitals, to bid against each other for limited protective gear.

This forced our front-line health care workers to resort to wearing trash bags, snorkel masks, and other ineffective alternatives when they could not get appropriate medical supplies.

Access to sufficient PPE, like N95 respirators, face masks, gloves, and gowns, could have helped save lives, including the nearly 4,000 health care workers who gave their lives on the front lines to fight this pandemic.

Even though we had limited information about how this virus spread when cases first started spiking in the United States, the warning signs about our supply chain were already there.

As early as July 2019, the Federal Emergency Management Agency (FEMA) outlined that a "worst-case" pandemic scenario, like COVID-19, would result in a shortage of medical supplies, beds, and health care workers as hospitals became overwhelmed.

In December 2019, I released a report warning of the serious national security risks posed by our overreliance on foreign nations for critical drugs.

Last Congress, I pressed for legislation to help increase domestic production for critical drugs and medical supplies to address these threats, and I am going to continue working with my colleagues to find common-sense solutions to ensure that our Nation is better prepared in the event of a future crisis.

I want to thank our witnesses for joining us today, and I look forward to hearing their perspectives on the challenges our country faced, the impact these shortages have had on health care workers and the public, and how we can strengthen our medical supply chain to prevent a similar disaster in the future.

We have received significant interest in this hearing, and I now ask unanimous consent (UC) that all statements submitted to the Committee, including those from the American Hospital Association (AHA), Michigan Hospital Association, Henry Ford Health System, Munson Health Care, Sparrow Health System, Trinity Health, and Premier, be entered into the record.<sup>1</sup> Without objection, the Statements will be entered into the record.

I understand my Ranking Member is being delayed on the floor. He will be here shortly. He can present his opening remarks at

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<sup>1</sup>The statements submitted for the Record appears in the Appendix on page 231.

that time, so we will move forward with the witness testimony at this point.

It is the practice of the Homeland Security and Governmental Affairs Committee (HSGAC) to swear in witnesses, so if you will stand and raise your right hand, and the witness online, if you could at least raise your hand, if not stand, that would be great. Do you swear that the testimony you will give before this Committee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Dr. ELNAHAL. I do.

Mr. HANDFIELD. I do.

Mr. SCHONDELMEYER. I do.

Ms. GLAS. I do.

Chairman PETERS. You may be seated.

Our first witness today is Dr. Shereef Elnahal, the president and chief executive officer (CEO) of University Hospital in Newark, New Jersey.

I will give a more complete opening to you before your testimony, but I am pleased that we have been joined by the Ranking Member, who scurried from his duties on the floor of the Senate to be here. Thank you very much, Ranking Member, and you may proceed with your opening comments.

#### **OPENING STATEMENT OF SENATOR PORTMAN<sup>1</sup>**

Senator PORTMAN. Thank you, Mr. Chairman, I look forward to hearing from the witnesses today.

Last month we did hold an oversight hearing on this general topic to help us understand some of the early failures that reduced the effectiveness to the pandemic response, and this is a continuation of that. I was pleased that at the last hearing, we tried to get politics out of it and focus on solutions.

Today's hearing is going to focus on a really important aspect of the pandemic response, which was the supply chain vulnerability that we all experienced and continue to experience, and to help this Committee, in my view, to develop legislation to help solve these problems for the future. I think we owe it to those who lost their lives during this pandemic and all the disruption it has caused to get this right.

We studied this issue because it became apparent that by the time the virus reached our shores, there was little we could do to prevent the shortages of critical supplies. The spike in demand for medical supplies was too high, the production of those supplies too far away, and too centralized in places hit hard by the virus. At the same time, the Strategic National Stockpile (SNS) was underprepared. The roots of these issues extend far past December 31, 2019, when a cluster of cases was first reported in Wuhan, China.

So what does this mean? Preparation for the pandemic should have begun years in advance, obviously. The constraints experienced by Federal, State, and local agencies, as well as hospitals, responders, and front-line workers, is the result of a supply chain and preparedness culture that seems to have suffered a failure of imagination regarding those worst-case scenarios.

<sup>1</sup>The prepared statement of Senator Portman appears in the Appendix on page 121.

While many factors contributed to our poor state of medical supply preparedness—which we will discuss here today—the State of the Strategic National Stockpile is chief among them, and that is our responsibility here in the Federal Government. The stockpile’s mandate has been to respond to discrete emergencies, not a simultaneous 50-State pandemic. For more than a decade, the stockpile focused on local chemical, biological, radiological, and nuclear (CBRN) threats often at the expense of pandemic preparedness. It did respond more effectively to the H1N1 pandemic with millions of PPE items and antivirals, but those were confined outbreaks, and the stockpile was never replenished after that episode. In the intervening years, of course, the stockpile’s mission has continued, but it has been less of a pandemic response and the question is, Why?

Compounding these preparation failures by the stockpile, the past two decades have seen a consistent offshoring of medical supply manufacturing. We all know about that; we will hear about that more today, particularly the United States relying on China for 75 percent of sanitary and hospital bed articles and 50 percent of our PPE, including N95 masks.

Today I look forward to hearing from our witnesses on three broad questions.

First, what steps should the United States take to reduce over-reliance on foreign countries for critical medical supplies? We need to understand how to diversify supply chains away from China, reshoring manufacturing to the United States, and incentivizing production in the Western Hemisphere.

Second, how do we foster a strong “Industrial Commons” for medical supplies here in the United States? It is a key part of our competitiveness going forward, I think. It is where you have a manufacturer, you have suppliers, inventors, skilled workers, and distributors, all networked and integrated together. It is not just about assembling gowns or pharmaceuticals, but about building out a supply chain that brings together the producers of the components of those items with the innovators also. These networks offer efficiencies, make it more difficult to offshore in the future, and increase innovation.

Third, as we develop this effort for medical supplies, how do we ensure that we have the right supplies, in the right quantities, and effective distributions for the future crisis? I also am concerned about the inadequacies of the SNS, as we talked about—the stockpile. Going forward, we need to properly define the role of that stockpile and be sure that it has the resources and capabilities we need to succeed.

Thanks again to our witnesses for testifying today, I look forward to hearing your thoughts on the path forward and, of course, look forward to continuing our approach to this, which I hope can remain nonpartisan and focused on actually how do you come up with solutions so that we can be more prepared in the future.

Thank you, Mr. Chairman.

Chairman PETERS. Thank you, Ranking Member Portman.

Our first witness today is Dr. Shereef Elnahal, the president and chief executive officer of the University Hospital in Newark, New Jersey. Dr. Elnahal is a physician who previously served in health

care leadership roles in the public and private sectors, including as the 21st commissioner of the New Jersey Department of Health.

Welcome, Doctor. You are recognized for your 5-minute opening comments.

**TESTIMONY OF SHEREEF ELNAHAL, M.D.,<sup>1</sup> PRESIDENT AND CHIEF EXECUTIVE OFFICER, UNIVERSITY HOSPITAL, NEWARK, NEW JERSEY**

Dr. ELNAHAL. Thank you, Chairman Peters, Ranking Member Portman, Members of the Committee on Homeland Security and Governmental Affairs, and my fellow panelists.

My name is Dr. Shereef Elnahal. I am president and CEO of University Hospital in Newark, New Jersey.

I thank the Committee for the opportunity to offer insights into my institution's experiences during COVID-19. I will also say that the Pharmaceutical Accountability, Responsibility, and Transparency (PART) Act and Help Onshore Manufacturing Efficiencies for Drugs and Devices (HOME) Acts would have helped my hospital better meet the care needs of our community during a difficult time, and I thank the Committee for a bipartisan effort to take action on this issue.

University Hospital is New Jersey's only State hospital and one of only 962 State and local government-run community hospitals in the United States. We are the Level 1 trauma center for the densely populated northern New Jersey region. We are an academic medical center and the principal teaching hospital for all Newark-based medical education, including Rutgers New Jersey Medical School—a robust, preeminent training ground for the next generation of health care heroes.

Last year, we had more than 83,000 emergency room visits, admitted some 15,000 patients, and had 200,000 outpatient visits. As one of New Jersey's safety net hospitals, we serve as a critical health care provider for a large population of low-income and Black and brown residents.

COVID-19 brought us circumstances that we had never seen before in health care—and things we hopefully will never see again.

As the number of COVID cases in our emergency rooms and intensive care units (ICU) multiplied, we found ourselves at risk of running out of supplies that we had never seen depleted before. This includes protective equipment for our staff and ventilators for patients who needed it.

These vital supply shortages affected the entire health care system, not just us, but the things that we needed the most were the exact same resources that every hospital needed. And so all hospitals were working their contacts in the global supply chain at the same time. Suppliers, therefore, serviced the highest and largest bidders, and safety net hospitals and stand-alone hospitals like ours were frequently the last to be called back.

Key medications, especially those which are used to sedate patients on ventilators were also dangerously low. Failing to sedate someone on a ventilator is agonizing for the patient. As professionals dedicated to healing, this was an outcome that we refused

<sup>1</sup>The prepared statement of Dr. Elnahal appears in the Appendix on page 217.

to accept, and so we worked around the clock on these issues to help patients survive COVID.

No patient, thankfully, went without such medications, but we were days away from this out in the most critical of times. In many cases, we needed to find suppliers with whom we had no track record and who we had no history of serving the U.S. medical community. At the same time, we were keenly aware that fraud was happening at many angles across the country. Occasionally, we needed to return or discard deliveries when items purchased were discovered to be ineffective.

For decades, this country has struggled to appropriately focus on the Strategic National Stockpile which must also be an important focus. I should also mention that the Coronavirus Aid, Relief, and Economic Security (CARES) Act did save our hospital, and I thank the Committee and every Member of Congress who helped enact that. Without the funds that kept our hospital afloat during the worst of this, we could not only not afford the supply chain materials we needed, but also we could not keep our doors open by August 2020. And so hospitals simply cannot fail during a pandemic, and the quick action of the Federal Government helped tremendously.

Aside from Federal assistance, New Jersey's State government—including strong support from Governor Phil Murphy—helped University Hospital get our fair share of the national stockpile. Our important work did not stop with patient care. In fact, we were one of the few sites nationwide that conducted the Moderna vaccine trial in a majority-minority community. We were the first hospital to administer a vaccine in New Jersey outside of a clinical trial, and we continue to provide all three approved vaccines to our community.

We did many virtual town halls to reassure our community that they can trust the vaccine, helping to quell the justified mistrust in the health care establishment dating back to slavery and the horrors of the Tuskegee experiment, but also acknowledging the implicit bias that people of color continue to experience to this day. More and more people in the community we serve accepted the vaccine over time, and now the challenge is access. We have re-routed our vaccination strategy in recent days to be where people are with mobile vaccination efforts in collaboration with our city, county, and State governments, and we hope that more organizations will join us in this line of effort. Without efforts to shore up the vaccine components and the supply chain, none of this would be possible.

Today we are in the final miles of the pandemic, but our public health crisis is not completely over. The reality is I am still not convinced that we are prepared for the next pandemic—whether from a vaccine-resistant variant of COVID-19 or a different pathogen altogether. While we are better off now as a result of many of the initiatives from the Biden administration on supply chain resiliency, there is still much work to do.

Still, there remains the matter of financial solvency for institutions like University Hospital. We need meaningful, value-based payment reform sooner rather than later.

When the pandemic struck, there was never a higher demand for health care in American hospitals, and yet the financial risk for

hospitals and health systems was never higher. This fundamental disconnect between payment and value has existed for decades and forced hospitals with thin margins to use just-in-time inventory practices for these very critical items that we were short on.

Thank you for the opportunity to provide our perspective, and I look forward to your questions.

Chairman PETERS. Thank you, Dr. Elnahal. We appreciate your opening comments.

Our second witness is Dr. Robert Handfield, professor of supply chain management in the Poole College of Management at North Carolina State University, and the executive director of the Supply Chain Resource Cooperative. In March 2020, Dr. Handfield began consulting various national supply chain task forces responding to COVID-19, including the Department of Defense's Joint Acquisition Task Force. Dr. Handfield has also served as a supply chain consultant to Fortune 100 companies in health care, pharmaceutical, and industrial manufacturing.

Dr. Handfield, welcome to the Committee. You may proceed with your 5-minute opening statement.

**TESTIMONY OF ROBERT B. HANDFIELD, PH.D.,<sup>1</sup> PROFESSOR,  
POOLE COLLEGE OF MANAGEMENT, NORTH CAROLINA  
STATE UNIVERSITY**

Mr. HANDFIELD. Thank you, Senator Peters, and thank you to the Committee. Good afternoon. My name is Rob Handfield, and I currently serve as a professor at NC State. I have studied supply chains for more than 30 years. I have published about them in a number of journals, and I have been a consultant, as you say, to many companies in health care, but also in government, including the Veterans Affairs' (VA), the General Services Administration (GSA), and the Department of Defense (DOD). I am familiar with government acquisition.

As a pro bono consultant with the DOD Joint Acquisition Task Force (JATF), I provided advice, market intelligence, and analysis for the supply of PPE, ventilators, and pharmaceuticals. I also interviewed chief procurement officers (CPO) in every State in the country to understand their challenges in obtaining PPE. Our team presented our recommendations for the SNS 2.0 to the Principal Deputy Assistant Secretary of Defense for Logistics at Office of the Secretary of Defense (OSD) in May 2020.

In my testimony today, I will describe the State of the Strategic National Stockpile prior to COVID and the events that occurred early in 2020, as well as some of the suggested reforms that I believe are necessary for future public health emergencies.

I would first like to state that my testimony is in no way intended to be acrimonious when it comes to the hardworking men and women who worked in the SNS during COVID. My critiques here are limited to the design of the SNS and government agencies as opposed to a direct criticism of the people working in it.

Prior to COVID, the SNS was somewhat of a "secret" organization. They did not publicize what they did. They were largely founded as a response to bioterrorism, and they were never in-

<sup>1</sup>The prepared statement of Mr. Handfield appears in the Appendix on page 130.

tended to be able to respond to pandemics such as COVID. Most of the people who worked there worked as inventory analysts, not supply chain experts. The decisions as to what inventory to stockpile for potential threats was determined by scientists within the Department of Health and Human Services (HHS) who often have a clinical view of public health risks, but do not often understand how supply chains get these materials to hospitals.

So there are a number of problems which I observed during the first half of 2020 in my work, and I have summarized some recommendations for each of these.

First of all, a lack of supply market intelligence and expired inventory left the government ill prepared for the pandemic. The SNS was running blind in managing the supply chain. The response was too little too late.

For the SNS to be better prepared, a multi-agency inventory portfolio based on in-depth supply market analysis is needed. This requires a supply management team that tracks the condition of critical supply markets for medical supplies, the supply risks within those markets, and acquisition strategies to manage those risks.

Second, a lack of material visibility technology across the SNS, FEMA, and State procurement offices led to a poor estimation of demand forecasts and the inability to detect shortages in health care networks. You cannot manage what you cannot see. The SNS needs an inventory visibility system tied to a control tower that tracks what is happening in real time.

During the COVID response, no one knew where products were coming from, where they were being sent, and who was receiving them. Material can be tracked through bar codes across a trusted network of hospitals, distributors, and manufacturers. This is not expensive technology and is relatively easy to deploy.

Third, the U.S. health care system relies on suppliers that are primarily overseas and leaves us at the mercy of export policies and priorities of other nations, which led to shortages. So this is a problem which we cannot fix easily overnight. It requires a more nuanced set of policies. Reshoring all health care products is not practical or cost-efficient, and it is not clear who invest in this.

While I agree that critical pharmaceutical products can be manufactured efficiently in the United States, we need more of a customized strategy for different categories of health care products, which I have outlined in my written testimony.

Fourth, disparate communication, lack of governance, or decision rights and ownership of issues among public agencies resulted in poor decisionmaking during pandemic. We observed a systemic failure at response across multiple agencies and firms. What we need is a playbook for how supply chain experts will work alongside public health experts in a disciplined manner using a structured response.

Fifth, States were competing with one another for material. This is because there is no existing policy on how to distribute material in an emergency. We need an equitable and fair means of deploying material in the stockpile that is based on need and avoids random allocations. Today no such policy exists.

Finally, contracting with distributors to hold inventory warehouses and holding them accountable for distribution in an emer-

gency was clearly not a reasonable solution. We need alternative contracting approaches for the SNS 2.0, contractual incentives with vetted suppliers and government agencies like the VA that can create an effective way to turn around inventory without it becoming expired.

To conclude, the idea behind the SNS is not so much to focus on resiliency but immunity to shocks that might occur. American exceptionalism became American hubris, and a system failure to respond was the result of poor events planning on the part of multiple agencies. The model I proposed is a significant departure from previous versions of this agency, but what we need is a bold and innovative strategy for supporting our national response to public health emergencies. I have outlined a set of solutions and would be willing to support these efforts in any way moving forward.

Thank you very much.

Chairman PETERS. Thank you, Dr. Handfield, for your testimony.

Our third witness, Dr. Stephen Schondelmeyer, is a professor of pharmaceutical economics in the College of Pharmacy and co-principal investigator of the Resilient Drug Supply Project at the University of Minnesota. Dr. Schondelmeyer also has more than 45 years of research and experience studying the pharmaceutical marketplace.

Welcome, Doctor. You may proceed with your five-minute opening remarks.

**TESTIMONY OF STEPHEN W. SCHONDELMEYER, PHARM.D.,  
PH.D.,<sup>1</sup> PROFESSOR, COLLEGE OF PHARMACY, CO-PRINCIPAL  
INVESTIGATOR, RESILIENT DRUG SUPPLY PROJECT,  
UNIVERSITY OF MINNESOTA**

Mr. SCHONDELMEYER. Great. Thank you, Chairman Peters, Ranking Member Portman, and Members of the Committee, for this opportunity to provide input on the resilience of the U.S. drug supply.

First, I would ask, What was the state of the U.S. drug supply prior to the pandemic? Let me remind us that virtually everyone needs prescription drugs at some point in their life. Americans have come to count on critical and essential medicines for serious and life-threatening diseases such as diabetes, epilepsy, or cancer, and we expect that these essential medications will be available at a nearby community pharmacy or the local hospital when they are needed.

Even before the pandemic, though, drug shortages were a serious problem and recurring problem with a web of factors in an opaque drug production and supply system.

We have tracked and reported on drug shortages for more than two decades, and these reports show that we have had more than 170 drugs in shortage at every point in time since 2014 or before. That is 170 drugs in shortage at every point in time.

This current and ongoing rate of drug shortages in the United States is unacceptable, yet for some reason, the market has failed to support the sustainable presence and availability of these drugs in the market.

<sup>1</sup>The prepared statement of Mr. Schondelmeyer appears in the Appendix on page 152.

What was the impact of the pandemic on the drug supply chain? The medical and drug supply chains have not escaped the monumental impact, and they experienced a triple threat during the first year of the pandemic with extreme increases in demand, unexpected disruptions leading to decreased supply, and exposure of systemic vulnerabilities.

COVID dramatically impacted the demand side for drugs in the United States and worldwide, with the most severe shortages for critical drugs such as propofol, midazolam, azithromycin, and other drugs. In fact, 40 critical COVID-19 drugs that were identified by the Resilient Drug Supply Project had 70 percent, or 28 out of 40, that were in short supply as recently as January 2021. That is, 70 percent of the critical drugs are still in short supply.

The rate of drug shortages is simply unacceptable, whether in times of pandemic or not. COVID-19 jolted the global pharmaceutical market at all levels and at many production points. The supply side disruptions from factory closures, shipping delays or shutdowns, and trade limitations or export bans and barriers.

Vulnerabilities of the U.S. drug supply chain have become more noticeable during the pandemic, including, but not limited to, heavy dependence upon foreign sources of drug production; old factories, equipment, and outdated manufacturing processes; below-margin prices for older, well-established generics due to overcompetition; lack of upstream visibility by purchasers, policymakers, and key stakeholders; and lack of a nationally coordinated policy approach to the pharmaceutical market. I would remind you the pharmaceutical market represents four percent of the U.S. economy, yet we do not have a policy approach as to how to manage and move that market forward.

In October 2018, the University of Minnesota initiated its Resilient Drug Supply Project. First, we examined the drug supply chain based upon country of origin for active pharmaceutical ingredients (API) and for finished drug products. When we looked at the top brand, generic, and critical access drugs, we found that nearly all drug products have the name of a U.S.-based company on the label or a U.S. subsidiary of a foreign company. From the downstream perspective, nearly drug products in the U.S. market appear to be U.S. products. But when we looked at the opaque upstream supply chain, we found that as much as 80 percent of the finished drug products were made outside of the United States, and as much as 90 percent of the active pharmaceutical ingredients were foreign-made. Most of the brand products were made in Europe. Most of the generic products were made in India, with up to 70 percent of their key starting materials being provided by China. Most of the critical access drugs were made in either China or India, and about 20 percent had totally undisclosed sources in the market.

While production of pharmaceuticals in foreign countries is not necessarily a bad thing, the current level of dependence on foreign sources in the U.S. supply is concerning. There is a long-term vulnerability of U.S. dependence on foreign sources for these critical medications. It places undue opportunities for political and economic leverage in the hands of other countries over the United

States. We could find ourselves held hostage by other countries that dominate the production of certain categories.

I have listed in my report four or five actions. One is we should have a defined process and infrastructure for analyzing, predicting, managing, and preventing shortages of critical medications.

Second, we should have an ongoing, in-depth map of the U.S. drug supply.

Third, we should authorize and fund a national entity that builds this map and analyzes the drug supply to coordinate the development of national policy.

Finally, the U.S. needs to establish an ongoing research program on the resilience of the U.S. drug supply, including a sentinel system and a predict-and-prevent process rather than waiting for fail-and-fix.

Thank you.

Chairman PETERS. Thank you, Dr. Schondelmeyer, for your opening statement.

Our final witness today is Ms. Kimberly Glas, president and chief executive officer of the National Council of Textile Organizations (NCTO). Ms. Glas also serves as the appointed Commissioner to the U.S.-China Economic Security Review Commission. Ms. Glas also previously served as the Deputy Assistant Secretary for Textiles, Consumer Goods, and Materials at the U.S. Department of Commerce and spent a decade on Capitol Hill working on manufacturing, trade, and economic policy issues.

Ms. Glas, welcome to the Committee. You may proceed with your five-minute opening statement.

**TESTIMONY OF KIMBERLY GLAS,<sup>1</sup> PRESIDENT AND CHIEF EXECUTIVE OFFICER, NATIONAL COUNCIL OF TEXTILE ORGANIZATIONS**

Ms. GLAS. Thank you so much for the opportunity to testify before you today. As you noted, I am the president and CEO of the National Council of Textile Organizations, and I represent the domestic textile industry, which employs approximately 530,000 workers.

Last spring, when the PPE crisis was on the national news nightly, showing workers wearing garbage bags as gowns and reusing N95 masks, it was profound imagery. Our strong overreliance on Chinese raw material components and finished PPE production chains exposed a profound fragility in our supply chains and exposed a significant national security threat.

Years of offshoring this industry had severe ramifications that played out on the national stage for all of us to see. As the supply chains broken down and export controls from China and elsewhere were placed on certain items, it left us vulnerable in ways that we could have never imagined and I hope we will never forget.

To frame it in a military context, it was like being on the front lines and learning your supply chain had been cutoff. The U.S. textile industry stepped in to fill an enormous void, reconstructing supply chains literally overnight, producing over 1 billion critical PPE items such as face masks, isolation gowns, and testing kit

<sup>1</sup>The prepared statement of Ms. Glas appears in the Appendix on page 217.

swabs for front-line health care workers. They welcome the calls from the highest levels of our government and across the Nation and felt an enormous responsibility and pride to retool their production lines.

As one of my members put it: “The supply chains broke down. I understood this is our calling. This is why we exist, and this is why we must make these products in the United States of America.”

I come before you today with an urgent plea. We must get critical policies over the finish line immediately, or the very supply chains that were retooled and reconstructed will remain fragile and largely offshore. Several companies who retooled their production and have significant PPE capacity are now staring down bankruptcy. China has exponentially expanded its global dominance, and key segments of PPE production are going offshore once again.

I want to commend the Committee for your unanimous support last week in advancing the Portman-Peters Make PPE in America Act. This is critical legislation to address two significant issues: long-term Federal Government contracts and domestic Federal procurement of 100 percent made in America PPE. I have outlined several key policy recommendations in my testimony and will briefly touch on some here. This is how Congress could help moving forward.

We need to create strong domestic procurement rules for Federal PPE purchases and other essential products substantially similar to the Berry amendment and the Kissell amendment, which require 100 percent U.S. content from fiber production forward. The Berry amendment is an essential Department of Defense policy to ensure we have vertically integrated supply chains for our warfighters so we are not held hostage on overseas supply chains to protect our men and women in the military. We need similar rules to strengthen the supply chain for our health care workers for PPE.

We also need to expand the Berry amendment rules for other essential products and purchasing by the Federal Government to include Department of Homeland Security, Department of Justice (DOJ), and beyond. A strong industrial base for the textile industry means a strong industrial base for the PPE industry.

We must important forward-looking policies to shore up the Strategic National Stockpile and issue long-term contracts to incentivize investment in the domestic production of PPE manufacturing.

We must create Federal incentives for private sector hospitals and large provider networks to purchase domestically produced PPE. These are the predominant critical purchasers of PPE in non-pandemic times.

We must centralize U.S. Government contracting processes and standardize vetting procedures.

We need to continue to deploy the Defense Production Act to shore up the textile industrial base from raw materials to end products for all essential items, including PPE, and work closely with the U.S. industry on advancing those key investments.

We have to ensure we have strong trade policies that address dumping of imports and counterfeit illegal products and addressing the substandard products that we are importing to our shores.

We must support tariffs on PPE imports to help bolster U.S. businesses and workers as well as our FTA partners, and we also must expedite and prioritize regulatory approvals for U.S. PPE manufacturers to strengthen this U.S. industry. With the right policy framework, the domestic PPE supply chains built overnight can endure and grow, creating a level of self-sufficiency domestically that we have learned the hard way is essential to our national health and economic security. Our industry stands ready to help this Committee, Congress, and the Nation's public health.

Thank you for the opportunity to testify today.

Chairman PETERS. Thank you, Ms. Glas, for your testimony.

As the COVID-19 pandemic spread in April and May of last year, we know the first responders and health care workers were facing really dire shortages of critical drugs and personal protective equipment, and as Ms. Glas talked about, doctors and other health professionals were sometimes forced to reuse masks, were wearing ponchos, using trash bags. Those images were pretty startling for us to see. Hospitals across my State as well as around the country were scrambling to find critical drugs, including those needed to assist patients on ventilators in particular.

Dr. Elnahal, this question is for you. You were on the front lines there. You saw it firsthand. I think it is important for the Committee's record for you to talk a little bit about the impact of the lack of available drugs and PPE on your hospital and hospitals like you. Please go a little bit more in-depth as to the dire circumstances you found yourself in so we know what we are dealing with here.

Dr. ELNAHAL. Thank you, Chairman, for the opportunity to provide that perspective. So imagine having the sickest patients that folks have ever had to treat come in at first and, fives, tens, and then 20 to 30 admissions a night into my hospital, having to retrofit parts of my hospital that do not normally care for such patients because we simply did not have the room, including expanding into our mother-baby unit, pediatrics unit, and asking those staff, who really never care for adults in respiratory distress, to do so not only in a manageable number, but sometimes nine, ten patients at a time. Then to add to that the lack of availability of PPE or medications that will keep someone asleep while they have a breathing tube down their throat, this was just a tremendous amount of stress that piled on what otherwise would have been already a very difficult situation.

And so not only were our leadership hand in hand with our front-line heroes, carrying boxes of PPE, isolation gowns, and everything in between to units themselves, we were on the phone ourselves with suppliers basically begging them to pay attention to our needs at a time when you had Goliath systems doing the same and sometimes cooperating with each other to make sure that they combine their purchasing power to acquire that PPE.

We depended asymmetrically on the Strategic National Stockpile materials, which makes that area of policy especially germane to safety net hospitals like ours which serve the most vulnerable; but also we really had to contend with the shortage of many critical

medications and increases in prices on medications that were specifically helpful for COVID-19. To have all those stresses on your as a clinician but then on top of that not feeling like you have what you need to adequately treat your patient and also broker conversations with family members and patients who are dying, sometimes our health care heroes were the only folks by the side of our patients as they were deteriorating and doing FaceTime and virtual conversations with family and loved ones. Just a tremendous amount of stress that just hopefully drives home the importance of this issue.

Chairman PETERS. Thank you for that, Doctor, and certainly your testimony clearly confirms what we all know. The men and women on the front lines are truly heroes, ones that we owe an incredible debt of gratitude as they put their own lives and families' lives in danger to help those who are suffering. So our thanks from the entire Committee, and thanks to all the men and women who are heroes in our country.

Dr. Handfield, you had contact with administration officials responsible for providing medical supplies, and when it was clear that the Federal Government was not prepared to address drug and PPE shortages, what actions should have been taken to adequately support State and local hospitals? If we had a do-over, what should we be doing?

Mr. HANDFIELD. Thank you for the opportunity to address that, Senator Peters, and, by the way, I was on the faculty at Michigan State for 10 years, so go, Spartans.

So, early on the SNS did have early indicators of a pandemic. On January 29th, they issued an analysis logistics summary, a new reporting mechanism that was piloting for the first time, and that early warning on January 29th asked for a response from key distributors who also were on allocation with China. So by February 3rd, all the distributors were being slammed with requests for PPE, and, I think a lot of the people in the SNS did not understand how that supply chain was designed and how much of it was located overseas.

What should have happened is—I think this is where we need to have acquisition supply management professionals—to have those early warning indicators and also to be able to work with other agencies on predicting what potential problems might be on the horizon. I should note in 2017 there was something called the PHEMCE, Public Health Emergency Medical Counter Measures Enterprise (PHEMCE), and they issued a strategic plan which outlined the key areas for inventory investment for the SNS. Number one on that list was \$5.7 billion for pandemic influenza, as well as development of vaccines with Biomedical Advanced Research and Development Authority (BARDA).

So this was an excellent plan to be better prepared. Unfortunately, this excellent plan was allowed to languish in 2018 and was never restarted. This was tragic, because I believe that if we had executed on this plan, we would have been in a much better place if it had been carried out.

For instance, the supply of N95 masks in the SNS inventory was acquired during the 2009 severe acute respiratory syndrome (SARS) epidemic. Those masks were acquired with one-time sup-

plemental influenza funding, therefore, were never replenished; and when COVID hit, most of them were expired and useless.

In addition, \$2.3 billion had been allocated on anthrax vaccines that were never shown to be effective for a threat that was never validated, which dated back to 2004. So wasting budgets on things like anthrax vaccines instead of real credible threats like pandemics is facilitated by having better market intelligence, better advance planning, and allocation of inventory to a portfolio that is based on risks in conjunction with public health experts that we can find across multiple agencies.

Thank you.

Chairman PETERS. Thank you.

Ranking Member Portman, you are recognized for your questions.

Senator PORTMAN. Thanks, Mr. Chairman. I appreciate all the experts who are here today.

Let me just start with something simple. We know from data that we have been able to uncover that 70 percent of the medical protective gear that we needed in the United States was based on China, and in February 2020, China nationalized medical supply production and imposed export controls, of course, on many of those critical supplies because they wanted them for their own citizens.

So the first question is just for all four of you, a quick yes or no. Do you think we were too dependent on China? Yes or no.

Ms. GLAS. Yes.

Mr. SCHONDELMEYER. Yes.

Dr. ELNAHAL. Yes.

Mr. HANDFIELD. Yes.

Senator PORTMAN. OK. That is a good start. It was 70 percent, but also it was not a reliable supply, obviously, given the fact they put the export controls in place, making it even worse, despite a lot of competition from around the world. So that dependence impeded our COVID-19 response, right? No question about it. And the question is, what do we do about it?

One of the things that we have talked about today and we are trying to figure out is how to make more PPE here, but use market forces to do it, so make it make sense. We have manufacturers here in this country who are willing to make stuff, but they need to know that they have a market. If they do not, they cannot make the significant investments, millions of dollars, to be able to convert their plants. This has particularly been tough on the textile industry, and, Ms. Glas, I want to thank you for being here, but also for your hard work in support of this Make PPE in America Act, which you mentioned we introduced and was passed in the Committee just last week.

In 1991, 56 percent of all clothes purchased in the United States were made in the United States. By 2012, it was 2.6 percent. So we have a big reduction in our textile manufacturing here. Has the general trend toward offshoring of apparel and textile products that we have seen over the last generation contributed to the specific lack of manufacturing of PPE during the pandemic?

Ms. GLAS. Undoubtedly, Senator Portman, absolutely 100 percent.

Senator PORTMAN. This goal, as you know, of the Make PPE in America Act is to require agencies to actually issue longer-term contracts. Why are long-term contracts an effective way to use those market forces to incentivize production here in the United States?

Ms. GLAS. Because, Senator, it provides a critical demand signal for our industry that there will be a purchaser and that they can invest in the new equipment necessary. We have Ohio manufacturers like Standard Textile who have looked at trying to invest more here in the United States, but they will not without a strong demand signal. A strong demand signal are long-term contracts. Other countries like Canada are issuing long-term contracts to their manufacturers to bolster production. Some of their contracts are as big and as large as 10 years because they know these are essential production changes.

Senator PORTMAN. As you know, I have had a great frustration with our Department of Defense in this area, in particular their refusal to issue those long-term contracts, which I never understood. At the height of the pandemic, they still were not willing to do it. But can you talk a little about the Department of Defense role here and what they could do better?

Ms. GLAS. So throughout the pandemic, there were several different purchasers across the Federal Government, including FEMA, Department of Defense, HHS, and a lot of these contracts were structured for 90 days, 120 days. While our industry responded overwhelmingly to those solicitations, that is not enough production time to invest in new equipment here in the United States and make a long-term commitment that you are going to make something here. We found so many fits and starts with the Department of Defense purchasing, not just in terms of the contract period but the vetting process associated with this and the kinds of products that there were conflicting demand signals that went to our industry.

In fact, I am just going to leave you this one anecdote. Our industry ran for a very short-term contract—I think it was 120 days—millions of yards of fabric for reusable gowns, that are sitting in warehouses that was never used because the government decided at the last minute that they wanted to purchase disposable gowns. That was because there was a lack of coordination across the government. DOD was purchasing for HHS, and the specifications and requirements were not—

Senator PORTMAN. Those are all things that can be fixed, and as you know, I am also not sure that disposable gowns make sense. I mean, why not have a gown that is reusable? It is so much a better deal for taxpayers, particularly that they tend to be better gowns and safer in terms of the use by hospitals in particular.

With regard to drugs, I just learned from you, Dr. Schondelmeyer, that 80 percent of finished drugs are made elsewhere; 90 percent of the components you said are made elsewhere, which was actually a higher figure than I had thought. I understand that labor costs are cheaper in places like China, and that China also intervenes in its economy in a non-market way to help their businesses. Are these the primary reasons that China is so

dominant in the manufacturing of active pharmaceutical ingredients, APIs?

Mr. SCHONDELMEYER. Sir, I think those are among the primary reasons, but it is a large and multiple factorial. I think China as a government has set the intention in certain therapeutic categories to become the dominant producer and influence those markets in ways that affect trade policy, in ways that allow them to dominate economically.

I would point out that just during this pandemic, of the active pharmaceutical ingredients made in China that are shipped to India to make products for the U.S. market, we have seen price increases of 100 percent, 200 percent, or more. China threatened to limit shipment of some products to India and the U.S. market. Although they have not acted on the threat, India itself did limit some exports of certain drugs for a period of time to the United States. So there are a number of factors, and those certainly are part of the process.

Senator PORTMAN. Any reason the United States cannot figure out a way to produce API here?

Mr. SCHONDELMEYER. We can. We have some. Actually, there is a new wave of what we call “green” manufacturing, people that use more efficient processes, cleaner processes that actually can reduce the cost compared to what it is costing in China given the old technology and the old processes. We could turn this around, but we have to have a concerted, developed national policy within the United States. To my knowledge, there is no agency that sets broad, industry-wide policy for the pharmaceutical market. The Food and Drug Administration (FDA) approves drugs’ safety and effectiveness, but they have no authority to look at economic and market-based factors. In fact, they are told not to.

Senator PORTMAN. That should be a priority, I would think, to learn from this. I have a lot of questions on the Strategic National Stockpile, and we do not have time to get all the answers. I do not want to go over my time because we have a lot of colleagues who want to talk. But, Dr. Elnahal and Dr. Handfield, if you could supply us with some more information on what the Strategic National Stockpile ought to be—clearly the 50-State pandemic was not something they prepared for, right? You have made that clear today. So that should be one criteria, to be prepared for this possibility. But we are going to submit some additional questions to the record for you all, and I would appreciate your getting back to us so that we can, again, try to put together some legislation that actually helps to move us forward and be better prepared next time.

Thank you, Mr. Chairman.

Chairman PETERS. Thank you, Senator Portman.

Senator Hassan, you are recognized for your questions.

#### **OPENING STATEMENT OF SENATOR HASSAN**

Senator HASSAN. Thank you, Chair Peters and Ranking Member Portman. To all of our witnesses, thank you for being here today.

Dr. Handfield, I am going to start with a question to you, and I am going to follow up a little bit on what Senator Portman was just talking about. At the beginning of this public health emergency, it became quite apparent that the Strategic National Stock-

pile, a key resource for responding to biological threats, did not have the necessary equipment or distribution capacities to adequately respond to the scale of this disaster. Despite the important role that the stockpile had played in responding to, for instance, the H1N1 virus, key supplies such as N95 respirators, surgical masks, and gowns were not replenished ahead of the COVID-19 pandemic.

Dr. Handfield, moving forward, how can we ensure that the stockpile has an adequate and up-to-date supply of unexpired personal protective equipment at all times so that it can adequately respond to public health emergencies across the country?

Mr. HANDFIELD. I think, one of the challenges with managing a stockpile of inventory is just that, it is sitting there and it is getting old. So in order to maintain an inventory of material that is up to date, that is current, that is fresh, if you will, you need to turn that inventory.

In my written testimony and in several other papers we have written, what we are recommending is that there be what is called a “living stockpile.” What I mean by that is that the inventory for the stockpile can be kept in different places throughout the government. We have VA hospitals around the country. We have DOD depots. But what is also needed is what I would call an “inventory visibility system,” which would be able to keep track of where all this inventory is.

As I indicated, this is not expensive technology. It requires just bar codes, a large data lake, and we can monitor when these things are going to be expiring, and as they expire or are getting close to their expiration date, they can be used by VA hospitals, they can be used by regular hospitals, they can be used by distributors. They can be replenished on a real-time basis.

So this requires some investment in visibility systems to track what is going on. It would also require a workforce within the SNS that is much more focused on what I would call a supply and acquisition mentality that is monitoring what I would call the “market intelligence,” that is creating the intelligence of what is going on in that market and keeping apprised of that and continually updating their acquisition strategies.

Senator HASSAN. Thank you.

I also want to follow up a little bit on comments and questions that you have heard from both the Chair and the Ranking Member here. To both Dr. Handfield and Dr. Schondelmeyer, in the early stages of the COVID-19 pandemic, many patients struggled to access essential medications as we saw disruptions in supply chains that interrupted the manufacturing and shipment of some drugs and active pharmaceutical ingredients. One way to avoid this problem in the future is to add resiliency and redundancy to our medical supply chains by expanding domestic manufacturing of essential medications.

Drs. Handfield and Schondelmeyer, how can the Federal Government incentivize domestic production of essential medications—you began to get at this in your answer to Senator Portman—particularly generic drugs that are widely relied upon by seniors and individuals with chronic conditions? We will start with Dr. Handfield and then go to Dr. Schondelmeyer.

Mr. HANDFIELD. So that is an excellent question, and as you point out, a lot of the active pharmaceutical ingredients for generic drugs are produced in India and a lot of those raw materials are produced in China. The reason they are produced there is obviously low cost, and generics are inherently reimbursed by insurance companies, by CMS, and others, and there is a minimum cost that they will be reimbursed for. Clearly, somebody has to pay, and if we do bring some of those manufacturing sites back to the United States, we are going to have to take a look at what the reimbursements are going to be on some of those drugs.

It is great to have generics, but, if we are saving 5 cents or 10 cents on a prescription and we are forgoing the resiliency of our supply chain, we really have to question that. I think there will need to be multiple agencies involved in reviewing this recommendation. I do think it is very possible to bring it back here.

Senator HASSAN. OK. Thank you.

Dr. Schondelmeyer.

Mr. SCHONDELMEYER. Yes, I do think there are things we can do to encourage particularly generic production in the United States. The U.S. Government has already acted to engage a company called Phlow Pharmaceuticals to make active pharmaceutical ingredients in the United States using new techniques and processes that, as I said earlier, are less wasteful and lower cost. They have engaged with a company called Civica, which is a nonprofit generic company whose goal is to make drugs that are in short supply or overpriced in the marketplace and available to all players.

But I would point out we need more than just one example of each of those. We need to encourage other Phlow companies to develop and other either nonprofit or companies dedicated to low-cost generics in the marketplace at a profitable level. I think we can learn from the lessons of the textile industry and things they have done over time to encourage textile producers in the United States. But one thing I would point out is, in general, the pharmaceutical industry cannot turn around and beef up or start new production quite as fast as they can in the textile industry. They may be able to do it in two or three weeks. In pharmaceuticals, it may take months to years to have substantial increased new production facilities.

Senator HASSAN. Thank you. I appreciate that.

Another question for you, Dr. Schondelmeyer. Over the past year, we have seen the results of billions of dollars in taxpayer investment into the development of life-saving COVID-19 vaccines and therapeutics. While not all companies that produce these technologies accepted funds specifically for development of these projects, they all significantly benefited from government-funded research that informed their approach as well as in some cases the guaranteed sale of their product.

So how can we ensure that the pricing of COVID-19 vaccines and therapeutics reflects the significant taxpayer investment after the end of the public health emergency?

Mr. SCHONDELMEYER. I think we need to apply basic principles we do for all things that are purchased by the government. We need to assure accessibility to those who need it. We need to assure affordability, that we can afford it either on the Federal fisc or as

individuals or as part of the health system. We need to assure accountability. Are the costs they are telling us that they have really bona fide costs, or are they simply lining the pockets of the top executives or shareholders beyond what is needed to induce production in the market? So affordability, accessibility, and accountability all need to be accounted for.

Senator HASSAN. Thank you very much, and thank you, Mr. Chair and Ranking Member. I have additional questions I will submit for the record.

Chairman PETERS. Thank you, Senator Hassan.

Senator Johnson, you are recognized for your questions.

#### OPENING STATEMENT OF SENATOR JOHNSON

Senator JOHNSON. Thank you, Mr. Chairman.

Let me start out by pointing out the 800-pound gorilla in the room here. I come from a very competitive manufacturing background, and I can pretty well guarantee if there is demand for a product, it will be supplied as long as there is a price that is high enough to justify the investment and the manufacture of it. Unfortunately, in medicine, with CMS, with Medicare, with Medicaid, with so much government intervention in that marketplace, the Medicaid formularies—which I have tried to understand, and they are impossible to understand—that is the reason, I would argue, we have shortages.

So from my standpoint in trying to solve this problem, we need to as much as possible rely on the pricing mechanism and the pricing signals of the private sector. Obviously, during COVID, we had a breakdown of government. It started with not replenishing our national stockpile after 2009. I am not really looking to government to solve this problem very effectively, but we need government help in terms of working with the private sector.

The private sector obviously was not prepared for this because everything is on just-in-time, so we are going to have to be incentivized in certain areas to carry inventory.

Mr. Handfield, real quick, rather than have government agencies stockpile amounts and then have to come up with a whole new inventory system, computer system to keep track of expiration dates, why not spend money and contract with the private distribution system to boost their levels of inventory to the level we need for the national stockpile and automatically be integrated into their current systems? Wouldn't that make a whole lot more sense than trying to set up a whole new system?

Mr. HANDFIELD. To answer your question, Senator Johnson, that is definitely something that we can do, and drugs are primarily distributed by distributors, like the McKessons, the Cardinals of the world. I think alternative contracting approaches can be done to do that. I think, again, I would go back to my earlier point of visibility. We also need to ensure that they are actually holding that inventory—

Senator JOHNSON. Again, the private sector can do that, and I would much rather rely on the private sector providing that information than government agencies, which are rather opaque.

Dr. Schondelmeyer, I want to really talk about the supply chain on pharmaceuticals. We held a roundtable here in February right

when COVID hit, and we had Dr. Scott Gottlieb here, and I think that was where my eyes were really opened in terms of our vulnerability as it relates to our pharmaceutical supply. Everybody at that point was talking about the API. As I dug into this more, it really first starts with what they call “intermediate,” which is kind of an odd name because it is really precursor chemicals that primarily come from China. There are environmental issues with that, correct, in terms of—when is the last time we build a refinery, a chemical refinery here in the United States?

Mr. SCHONDELMEYER. There are some; they can be dealt with. But they are easier to deal with in China where they have higher levels of pollution.

Senator JOHNSON. Right, so, again, that is a constraint. We are going to have to overcome that if we want to bring—again, make sure that I have the supply chain right. First comes the intermediate, which is really the precursor basic chemicals, the refinery process, have environmental issues. It goes from those basic chemicals then into the active pharmaceutical ingredients, primarily India. India is a big part. We have to bring both of those back to a certain extent, correct?

Mr. SCHONDELMEYER. Either back to the United States or find diverse sources that are outside of China and India.

Senator JOHNSON. That is the other point I wanted to make in terms of looking to the supply chain. I do not think it makes sense to do 100 percent buy America. I think the more suppliers we have globally, it actually increases security as long as we are not totally dependent on any one country or any group of countries, and we obviously have some manufacturing capability here. I think the balance is how do you get the percent should we manufacture here in America in terms of getting that accomplished. I think it is pretty simple in terms of drugs. You just have the FDA say if you want to supply a drug, an FDA-approved drug in America, it has to be manufactured here in America to this extent, recognizing, though, that that is going to increase costs, and I get back to the 800-pound gorilla in the room here, is we limit the reimbursement to private sector companies, which is why we have 170 drugs that are in shortage perennially. Isn't that basically correct? Because if people could make money off these drugs, we would not have a supply shortage.

Mr. SCHONDELMEYER. In part, yes, but in part, no.

Senator JOHNSON. Tell me where I am wrong.

Mr. SCHONDELMEYER. I believe in the market, sir, very much and in westernized economic systems. But when it comes to drugs and when a drug is needed in the marketplace and is not available, the system will respond in the long run. Most economists will tell you that in the long run the system will clear out that process. But for the patient who needs that drug today or in the next few hours or they will die, they will die in the short run, and the market will not solve that problem.

Senator JOHNSON. If you have a steady demand for drugs, the market, I think, will respond. I know you were talking about 70 percent of the COVID-related drugs were in short supply. That makes sense. Nobody was prepared for this, and you could not really expect them to be prepared. But how many other drugs outside

COVID really have big supply and demand spikes as opposed to like heparin or things that just—you basically know what the demand is going to be year in and year out. You can plan on that.

Mr. SCHONDELMEYER. Even year in and year out, there are wide fluctuations in certain drugs. There can be variations. It is not all totally predictable, and that is partly why we got caught with short supplies and our just-in-time inventories that we had not planned for the amount of variation, even for our flu season, let alone a pandemic event.

Senator JOHNSON. OK. Again, I really do believe government's intervention in the marketplace, the payment, the limitations on pricing, really distorts the marketplace. I am not denying there are not other issues, but I think we really do need to go to the root cause of why we had, 170 drugs in perennial shortage. I think a big part of that is there is just simply not the profit motive for companies to maintain them.

But I think I am pretty much out of time. Thank you, Mr. Chairman.

Chairman PETERS. Thank you, Senator Johnson.

Senator Hawley, you are recognized for your questions.

#### **OPENING STATEMENT OF SENATOR HAWLEY**

Senator HAWLEY. Thank you very much, Mr. Chairman, and thanks to all the witnesses for being here.

Ms. Glas, if I could just start with you, you noted in your testimony—and this caught my eye—that U.S. textile manufacturers compete in one of the most unbalanced economic playing fields of any industrial sector. Can you give us a sense why that is the case? What role specifically has trade policy played in this?

Ms. GLAS. Thank you, Senator, for that question. Since the mid-1990s, we have seen a significant offshoring of this industry. There are a variety of reasons for that. The World Trade Organization (WTO) had quota phase-outs for textile and apparel products, the accession of the Chinese to the WTO, permanent normal trade relations with Vietnam, and the insatiable appetite for the lowest-cost producer, right? This played out on a national stage when COVID hit. How many U.S. textile manufacturers did I represent making PPE? Probably two or three. What happened during the pandemic? About 140 companies of mine retooled their production chains to help fight the crisis. Now a lot of those companies simply have no orders. They are starting to see Chinese imports come in for these products, obviously exponentially. Obviously, we are thrilled about the vaccine being deployed; however, we are starting to see products come in that are below cost, the dumping of products coming into the U.S. market, and we have a U.S. industry who has invested, who want to make these products here, but with no demand signal, no long-term demand signal by the Federal Government. We have not solved the equation of how to get hospitals and nursing homes to purchase products that are made here in the United States. A lot of them have relied on foreign supply chains and distributor networks, and we need to change that equation if we want to make sure we onshore this long term.

Senator HAWLEY. Some of the hardship of this industry, you put at least some of it, maybe a lot of it, down to WTO-related policies,

agreements, changes that happened in the 1990s and the first decade of this century following China's admission to the WTO and its permanent most-favored-nation status, permanent trade status. Is that right? Have I got that correct?

Ms. GLAS. Yes.

Senator HAWLEY. Remind me of the employment impact again. What was the immediate employment impact of these—

Ms. GLAS. Over time.

Senator HAWLEY. Yes, I should not say "immediate," I suppose.

Ms. GLAS. The industry used to employ, I would say, 3 million workers in the 1990s, and now we are about 600,000 workers.

Senator HAWLEY. Wow, 3 million to 600,000, that is an incredible impact. Tell us why you think the deck is still stacked against domestic textile producers. You were started to allude to this with the folks who retooled to produce PPE. Now they do not have orders because they are seeing the imports from abroad that are much cheaper. But give us a sense of why you think the deck is stacked against domestic producers.

Ms. GLAS. Because we are not playing on the same level playing field, and, ironically, through this crisis, there was a New York Times report this summer that 50 factories sprung up in Xinjiang, and a number of those factories were making PPE for our domestic marketplace. It is hard to compete globally with a subsidized industry all over the world, including China. So we have domestic manufacturers who can be globally competitive. We just need to send them a strong demand signal, and we need to get policies over the finish line here in Congress to make sure that, yes, we can be more globally competitive, but people are not going to invest. But I am going to tell you the price points for some of the products, importation of some of the key products are below market value.

Senator HAWLEY. And so people realize, when you refer to Xinjiang, we are referring to the province where the Uyghurs, among others, are imprisoned. And so there is a possibility that this is exploited labor.

Ms. GLAS. Exploited forced labor.

Senator HAWLEY. Yes, it is hard for free labor to compete with exploited forced labor. Is that fair to say?

Ms. GLAS. That is correct.

Senator HAWLEY. Give us a sense of what you think some of the ways are that we can address these imbalances in our trade policy when it comes to PPE and textiles.

Ms. GLAS. I think we have to have a whole-of-government approach to trade enforcement. First off, we need PPE tariffs, and we also need to take a look at punitive tariffs associated with PPE now that we are through the crisis of the pandemic.

The other thing is we need to enforce our trade laws on environmental and labor standards and on forced labor. Customs came out with the withhold release order (WRO) to say that, we should not be importing products from Xinjiang or certain factories or cotton products. We need to hold them to their word, and we need to ensure that we are stopping importation of products that are suspected to be used with forced labor, and that requires Congress also providing a signal to the administration that, this needs to be enforced with the full throat of the U.S. Government.

Senator HAWLEY. Absolutely. Just to stay on China for a second, why do you think that China is well placed to expand its global dominance in this industry? Is it due to the exploited labor? Is that the biggest single factor?

Ms. GLAS. That, and the subsidization within this industry. You will see over a period of time the Chinese have invested significantly in raw material production, man-made fiber production in the country. Man-made fiber is the essential raw material that is used in PPE. So during the tight time in the crisis, we could not just get N95 masks. There were export controls on this. There were export controls on the raw materials, so we could not even get those out of the—they have continued to invest in this production chain, and it has been at our peril. We saw this play out on the national stage. In fact, I just pulled up the numbers. Since the beginning of the pandemic, Chinese imports into the United States have grown 756 percent. Two-thirds of our imports for PPE are continuing to come from China. While we have bolstered domestic production, I am going to tell you a lot of my members who retooled simply have no orders. So there is a sense of urgency to get something over the finish line here.

Senator HAWLEY. Thank you very much for that.

Just in my few remaining moments here, Dr. Handfield, could I ask you about your testimony? You write that in the 1970s companies producing medical supplies began to move their manufacturing abroad, and I wonder, in your assessment, what caused the shift? Is it related to the trade policies that Ms. Glas was just testifying about?

Mr. HANDFIELD. A lot of the offshoring of medical supplies to China occurred because of cost pressure, and at the time, hospitals and health care in general were under a lot of pressure to continually reduce costs. The channels through which they purchased PPE are health care distributors and what they also call “group purchasing organizations.” Their basic mode of operating is, well, if you buy in huge quantities, we will give you a big discount. So that incented them to go to the lowest cost.

What it has also done, however, as you pointed out, we have really hollowed out our ability to be self-sufficient when it comes to medical supplies. I think there are a lot of reasons why we can develop those products domestically, and another reason for it is we can produce it just in time. “Just in time” means you produce close to your customer, and so you do not have to carry as much inventory. It does not have to sit on a ship. It does not have to sit in a port. There are a lot of benefits to doing it domestically.

Senator HAWLEY. Very good. Thank you for that testimony. Thanks to all the witnesses.

Thank you, Mr. Chairman.

Chairman PETERS. Thank you, Senator Hawley.

Senator Rosen, you are recognized for your questions.

**OPENING STATEMENT OF SENATOR ROSEN**

Senator ROSEN. Thank you, Chair Peters, Ranking Member Portman. Really, thank you for holding this hearing. It is extremely timely and important, the pandemic, of course, highlighting so many vulnerabilities in our global supply chain. This is the time to learn and make improvement.

But I would like to talk a little bit about the nonprofit drug and device manufacturing, because before the pandemic there had been growing concern about, of course, both high drug costs and shortages of critical drugs and, of course, medical devices, the clear warnings about capacity in the event of a pandemic, and then COVID-19 hit. We saw health providers, first responders, most everyone has been testifying to the scrambling for gloves, masks, other kinds of PPE. What we have to do, of course, as everyone has been testifying, is strengthen our global supply chains and our domestic capacity moving forward.

One of the things I think we can do is to boost the nonprofit drug and device manufacturing sector in America. I am working on some legislation that would lower prescription drug costs, reduce drug shortages, boost domestic production, and create American jobs by providing Federal support for the nonprofit drug and medical device organizations.

Dr. Elnahal, as the leader of a major hospital, I have kind of a multi-part question here. What impacts do unpredictable drugs, medical devices, supply shortages, due to, of course, disruption in the supply chain, have on your ability to treat patients, No. 1? What is the impact when there is only one source, No. 2? How do you think the increased availability of a low-cost-option critical medications produced in the United States, how would that improve patient outcomes in your hospital?

Dr. ELNAHAL. Thank you, Senator, for the question. The first thing I will say is the obvious point, that it impacts patient care. So when you are days away from running out of a medication that allows you to ventilate a patient or to adequately treat them for a disease. You are forced to consider alternatives that may be inferior, or you may not be able to deliver care at all, and so this has real human costs and consequences, as my co-panelists have mentioned.

But, also, it is not just potentially running out of a medication. It is resorting to plans of care and treatment that are simply not optimal. From a medical, legal, and ethical standpoint, that is just unacceptable. I think we have a responsibility as a country to ensure that hospitals like mine can acquire and purchase what is needed to adequately deliver patient care, especially something as basic as intensive care that you provide to somebody who just simply cannot breathe.

Secondarily, as you mentioned, the costs can be prohibitive, and we have seen just serially increasing costs as a hospital and so many critical medications that we just cannot do without. When you have to do these on a sole-source basis, of course, the prices tend to be higher in contrast with the value necessarily received from them. The availability of generics and the availability of alternatives that are proven through medical evidence to be just as effective is really important, especially for the health care safety net

in this country. The fact is we are a public hospital, but the vast majority of our revenue is earned, despite the aid that we do receive from the States and Medicare and Medicaid Disproportionate Share Hospital (DSH). All of that really matters for us to be able to shore up our supplies and make sure we do not see a repeat of what happened last year.

Senator ROSEN. Hopefully my legislation and the nonprofit sector can help you there. But I would like to talk to another thing that really impacts our supply chain disruption, and that is, of course, cyber attacks. Last week, the Colonial Pipeline, of course, that is not health care, but it does affect lives and livelihoods if our fire departments or first responders, ambulances do not have gas, there could be electrical outages, any of those things. Cyber attacks against hospitals, local governments, businesses, other organizations, of course, are happening every day. They pose significant threats. And considering the challenges in our medical supply chain, any disruption could be deadly.

Dr. Schondelmeyer, through your work with the Resilient Drug Supply Project, as you map out supply chains, how do you account for expected and unexpected disruptions? You know, expected, you might have a hurricane or tornado. Unexpected, of course, are the cyber attacks that might paralyze one of your systems. How could we better support you in those efforts?

Mr. SCHONDELMEYER. We are still in the process of identifying the threats that could affect the drug supply system, but certainly cyber attacks are on our list of things that could happen. There we really need to work with the private market. The suppliers, the wholesalers, the group purchasing organizations, and others have fairly efficient and sophisticated information technology (IT) systems and cyber operations, but we need to work with them to make sure that they are secure and that we do not have an attack on the drug supply systems, supply chains, like we saw with the oil industry recently. That could be devastating to the country. If we cannot get the needed drugs out to the hospitals or to the community pharmacies, patients with diabetes and with heart attacks and with other critical conditions are literally going to die or suffer severe consequences from the absence of those drugs. Things that we once thought unthinkable are not anymore.

Senator ROSEN. Would you think it would be helpful to designate some of our drug manufacturers, some things in these global supply chains and maybe inpatient care settings as critical infrastructure? Because not just livelihoods but lives are on the line if there is disruption or attack.

Mr. SCHONDELMEYER. Yes, Senator, I certainly think that would be helpful, and we need to keep in mind that the critical infrastructure—they certainly are the large tertiary care hospitals, and they are critical. But there are also critical rural hospitals that are the only place for health care within, tens to hundreds of miles for some patients. We need to keep in mind health care institutions of all types and sizes, not just a certain type of health care institution, as being critical.

Senator ROSEN. I agree with you there. In rural Nevada, we have hundreds of miles sometimes to drive. Of course, those qualified

Federal health centers, all of those community-based care, are particularly important.

I appreciate you all for being here. I see that my time is about to expire. Thank you, Mr. Chairman.

Chairman PETERS. Thank you, Senator Rosen.

Senator Ossoff, you are recognized for your questions.

#### OPENING STATEMENT OF SENATOR OSSOFF

Senator OSSOFF. Thank you, Mr. Chairman.

Ms. Glas, thank you for your testimony today. Thank you to the entire panel. You noted in your testimony and have noted throughout this hearing that, particularly in the early months of the COVID-19 pandemic, severe PPE shortages impaired the medical response and also put front-line health care workers at unnecessary risk of infection. In the early days of the pandemic, health care workers were forced to use ad hoc, homemade solutions to protect themselves—trash bags, rain ponchos

The experience of Phoebe Putney Memorial Hospital in Albany, Georgia, is emblematic of how poorly prepared we were and what a failure to manage the medical supply chain and manage a surge in demand we saw in the execution of the Federal Government's response. As these PPE shortages swept across the country in the early months of the pandemic, nurses and doctors at Phoebe Putney Memorial Hospital in Albany were literally sewing their own face masks and producing their own protective equipment. I will never forget the images of nurses assembled in a room sewing homemade PPE so that they and their colleagues could continue to treat patients as we saw a huge surge in infections and a huge taxing demand on respiratory critical care and intensive care services at Phoebe Putney in Albany.

My question for you, Ms. Glas is: Have we taken the necessary steps since those early months of this crisis to ensure that our nurses and doctors and front-line medical providers such as those at Phoebe Putney in Albany are never again forced to sew their own face masks or don trash bags or ponchos to protect themselves in the midst of a deadly pandemic while they do their jobs treating patients and saving lives?

Ms. GLAS. Senator, thank you for that question, and that description of that hospital is a description of so many hospitals and institutions across our country. I had family members calling me who were desperately seeking PPE, and they were using substandard—whatever they could find to try to protect themselves.

I think this is a complicated question, Senator. Has our industry been able to retool and invest in some of this critical PPE? Absolutely. But where we are today and where we were in the spring of last year are two different scenarios. But what I am concerned about, Senator, is a few months from now those supply chains that we just constructed to help ensure that those hospitals did not have to sew their own masks will go offshore again. We are starting to see that. In addition, prior to COVID-19, there was one testing swab producer in the United States, and that producer has been invested in significantly by the U.S. Government. But there is no dramatic second producer here in the United States. When we are looking at Defense Production Act funding, we have a manufac-

turer in Ohio who can make testing kit swabs, but they are not sure if they are going to be in the business long term without the Defense Production Act.

We are going to need to diversify supply chains moving forward. We need to show a demand signal to the industry. There needs to be incentives for hospitals like the one that you have that want to purchase USA-made product that is going to cost a little bit more, and there are a lot of Georgia textile manufacturers that want to respond to your local hospital systems and make these products long term.

Senator OSSOFF. Thank you very much for that answer, Ms. Glas.

A question for you, please, Dr. Elnahal. As you consider potential future public health crises, whether a pandemic or otherwise, what are key medical products, types of medical equipment, for which there was perhaps not an extraordinary surge in demand during this COVID-19 pandemic, but for which there might be in other plausible public health crises so that we can begin now to prepare ensuring that the supply chains for other critical medical supplies that will be in high demand in a future crisis are robust and able to withstand a sudden surge in demand if and when such a crisis arises?

Dr. ELNAHAL. Thank you for the question, Senator. The first thing I will mention is that respiratory viruses and respiratory diseases are not the only things that can cause epidemics and pandemics. You have, for example, Ebola, which keeps resurfacing in Africa. Newark Airport, for which we cover emergency medical services (EMS) in New Jersey, was the site of one patient who was suspected for Ebola, which caused a national incident where essentially a nurse was forced into quarantine. And so something that we focus on is the possibility of Ebola coming, but also other pathogens that can cause gastrointestinal diseases and other types of disease. For each of those disease categories, you are going to have your characteristic needs. But I can tell you that personal protective equipment for every type of pathogen will be important.

The types of equipment will be different, depending on the specific disease. So, for example, pathogens that tend to cause diarrhea and are transmitted through the fecal-oral route, you really need to make sure that both disposable and reusable gowns are replenished and available. Isolation gowns for respiratory diseases and, contact-based diseases were an issue in this pandemic, but there are also different types of equipment specific to that.

I think the idea is to take a look at the possibility of epidemics and pandemics in multiple different disease categories and go down the list of everything that is needed. But we really should not be having shortages for commonly used medications of any type, and Dr. Schondelmeyer talked about that really eloquently, to reduce that volatility through effective policies, making sure that the stockpile is there and exists. There were no real medication stockpiles we saw for some of the sedating medications for folks on ventilators. All of that will be important in addition to policies that shore up manufacturing.

Senator OSSOFF. Thank you, Dr. Elnahal, Dr. Schondelmeyer, and Dr. Handfield, my time is running out. What I would like to

request of each witness is that you please submit for the record an itemized list of the medical equipment products,<sup>1</sup> the precursors for production of key medical supplies and products, the pharmaceutical products that may swiftly be in high demand and of which we may have shortages across a range of plausible public health crises that you might anticipate so that this Committee can refer to such lists as we consider other supply chains that may require reinforcement.

Thank you so much, and I yield.

Chairman PETERS. Thank you, Senator Ossoff.

Last Congress, I introduced two bills. One was called the “HOME Act,” the other was the “PART Act.” They were based on the findings of our 2019 investigative report that I mentioned in my opening comments where we saw the vulnerabilities that existed because of offshore production of critical supplies and drugs.

One thing that became quite apparent in the investigation is we do not have a good handle on exactly what is made in the United States, what is made overseas, what are the supplies, what are the manufacturing capabilities. Dr. Schondelmeyer, the PART Act is the act that deals with that. It would basically expand manufacturer reporting requirements to include increased demand, export restrictions, quarterly reporting on the amount of drugs and active ingredients that are here, what is overseas. It is difficult to put forward policies if you do not have a real clear picture of what is out there. Do you see a need for this type of legislation to increase supply chain visibility as we work on this problem?

Mr. SCHONDELMEYER. Absolutely. I think we know so little about our drug supply system, and many of the prescription drugs sold in the U.S. market, as I said, have on the label the name of a U.S. company or a U.S. subsidiary of a foreign company. But that almost always says “manufactured for” or “distributed by” or “marketed by.” Less often does it say “made by” or “origin” or “product of,” which tells you the country where it was really made.

We have a health care system and a pharmaceutical system that masks the origin and provides kind of a stealth, and we do not know where they come from. In testimony last fall, I remember the FDA admitted that they do not know and they do not have authority to collect volume and market production levels. I think your act specifies that, spells it out, and would give us some of the information we need to have this ongoing supply map so we know what we are doing when we need to find drugs in the marketplace.

I really watched the National Football League (NFL) draft, and it is amazing how much those NFL teams know about the football players they can select. We know so much less about the drugs that we rely on every day that it is dangerous.

Chairman PETERS. Yes, absolutely. Visibility and understanding the scope of the problem is the first step in order to try to solve this. That is the intent of that legislation, and we are going to be working on reintroducing it and certainly would welcome all the panelists’ input into that legislation.

The other act is the HOME Act, which then builds—after we have that understanding of potential supply shortages that could

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<sup>1</sup>The information requested by Senator Ossoff appears in the Appendix on page 296.

exist and where the manufacturing, once we understand those dynamics, we have to bring it onshore, and onshore will take a variety of strategies. The HOME Act talks about authorizing HHS to actually make investments in domestic advanced manufacturing of critical drugs and supplies through loans, perhaps forgivable grants, but also focused in a very strategic way as to those that we need to make those investments, and that requires obviously visibility as to what is out there, where it is manufactured, and the demand side as to what we need and make sure that we have to have that in our country, but understanding that we may have to take a proactive approach of investment in those industries.

Dr. Handfield, with that brief introduction, in your view, would something like that help us deal with some of the critical shortcomings in our current supply chains? Is that something that we should be exploring further?

[Pause.]

Mr. HANDFIELD. Yes, I am sorry. That was directed to me. I apologize. I really do believe that that approach would—as I said before, using alternative contracting approaches would make a lot of sense. First of all, I think you could target those drugs that are immediately in short supply which we know could be manufactured here. I have had some discussions with FDA, and I believe that there is greater discretion on their part of working with manufacturers to ensure that they meet the Good Manufacturing Practices (GMP) requirements to be able to do those quickly.

There are other parts of the supply chain that may take longer to move domestically. There may be complications in terms of regulatory issues. But we want to be able to identify those areas that are really critical bottlenecks in the supply chain, if you will, and it is those bottlenecks that are sometimes two or three tiers down the supply chain that are going to be the restrictive component that will halt and create those shortages.

I think it makes sense to start with the Prevent Auto Recycling Thefts (PART) Act, and manufacturers are going to be reluctant, to be able to share that information. I would venture to say that some of them may not even know what that information is or who is in their supply chain. And then the second part of that would be to say, well, what parts of that do we want to bring back to the United States? I think there are really, the right incentives, the right contractual incentives that can lead them to do that would make a lot of sense, and I would be happy to work further with you on determining what kinds of drugs would best fit those types of criteria.

Chairman PETERS. Thank you, Dr. Handfield, for that offer, and it certainly is interesting, the testimony that even the manufacturers' companies are not sure what is in that supply chain as well. So having greater visibility is going to be important for us to deal with this issue.

I want to thank all of our witnesses for engaging in this important discussion as part of this Committee's bipartisan oversight of the Federal coronavirus pandemic response. I think there is no question certainly from the testimony we heard here today that our longstanding overreliance on foreign sources for critical medical products, coupled with the Trump administration's failure to take

early action, led to mass shortages of needed PPE and critical drugs throughout the United States. As today's hearing demonstrated, the shortages we experienced and continue to experience, as we have heard, were and are foreseeable. Unfortunately, instead of acting quickly and understanding the severity of the virus, the past administration failed to effectively coordinate a unified response and procure the medical supplies that we needed.

As our Committee continues its investigation into the Federal response and identifies needed reforms, we look forward to building on the testimony that we have received here today. As we have seen from the dearth and destruction wrought by this virus, the cost of inaction is simply far too great to bear.

So, with that, the hearing record will remain open for 15 days, until May 28th at 5 p.m., for the submission of statements and questions for the record. With that, this hearing is now adjourned.

[Whereupon, at 4:03 p.m., the Committee was adjourned.]



## A P P E N D I X

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**Chairman Peters Opening Statement As Prepared for Delivery  
Full Committee Hearing: COVID-19 Part II: Evaluating the Medical Supply Chain and  
Pandemic Response Gaps  
May 19, 2021**

Today's hearing, the second in a series examining the federal government's response to the Coronavirus pandemic, will focus on vulnerabilities in our medical supply chain that were fully exposed last year, as the United States struggled to secure desperately needed supplies to combat the spread of COVID-19.

Despite years of warnings about the dangers of our nation's overreliance on foreign sources and manufacturers for critical medical supplies, our nation was still unprepared to acquire the masks, gloves, gowns and ventilators needed to treat the significant number of COVID patients, stop the spread, and save lives.

And while the federal government had plans in place and authorities available to help address these longstanding supply chain challenges, the Trump Administration failed to use them at the onset of the pandemic to coordinate an effective, unified federal response.

To date, this tragic and historic public health crisis has taken the lives of more than 586,000 Americans, left untold economic destruction in its wake, and resulted in long-term health consequences for thousands of Americans.

Thanks to the ingenuity of American scientists and the Biden Administration's actions to ensure rapid distribution of vaccines, there is light at the end of the tunnel.

However, as we learned in our first oversight hearing, the loss of life, the damage to the health and livelihoods of countless Americans, and the suffering caused by this pandemic, were not inevitable.

Swift, decisive action, and a comprehensive national strategy from the previous Administration, could have reduced the devastation this pandemic wrought on our communities.

The federal government should have taken early action to ramp up production of personal protective equipment, and other critical medical supplies, by issuing emergency contracts or fully invoking the Defense Production Act.

Instead, the Trump Administration left individual states to secure supplies and combat the virus on their own. Instead of a coordinated federal effort to secure and direct supplies where they were needed most, the Trump Administration's inaction forced states, and even individual hospitals, to bid against each other for limited protective gear.

This forced our frontline health care workers to resort to wearing trash bags, snorkel masks, and other ineffective alternatives when they couldn't get appropriate medical supplies.

Access to sufficient PPE, like N95 respirators, face masks, gloves and gowns, could have helped save lives, including the nearly 4,000 health care workers who gave their lives on the front lines to fight this pandemic.

Even though we had limited information about how this virus spread when cases first started spiking in the United States, the warning signs about our supply chain were already there.

As early as July 2019, the Federal Emergency Management Agency outlined that a “worst case” pandemic scenario, like COVID-19, would result in a shortage of medical supplies, beds, and health care workers as hospitals became overwhelmed.

In December 2019, I released a report warning of the serious national security risks posed by our overreliance on foreign nations for critical drugs.

Last Congress, I pressed for legislation that would help increase domestic production for critical drugs and medical supplies to address these threats.

I will continue working with my colleagues to find commonsense solutions to ensure that our nation is better prepared in the event of a future crisis.

I want to thank our witnesses for joining us today, and I look forward to hearing their perspectives on the challenges our country faced, the impact these shortages had on health care workers and the public, and how we can strengthen our medical supply chain to prevent a similar disaster in the future.

We have received significant interest in this hearing and I now ask unanimous consent that all statements submitted to the Committee, including those from the American Hospital Association, Michigan Hospital Association, Henry Ford Health System, Munson Health Care, Sparrow Health System, Trinity Health, and Premier be entered into the record.

Without objection, the statements will be entered into the record.

With that, I turn it over to Ranking Member Portman and thank him for joining me to conduct these oversight efforts with a strong, bipartisan approach.

**Opening Statement**  
**Ranking Member Rob Portman**  
U.S. SENATE COMMITTEE ON HOMELAND SECURITY  
& GOVERNMENTAL AFFAIRS  
*“COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic  
Response Gaps”*  
May 19, 2021

*“Thank you Mr. Chairman, I look forward to hearing from the witnesses today.*

*“Last month we held an oversight hearing on this general topic to help us understand some of the early failures that reduced the effectiveness to the pandemic response. This is a continuation of that. I was pleased that at our last hearing, we tried to keep politics out of it and focus on solutions.*

*“Today’s hearing will focus on a really important aspect of the pandemic response, which was the supply chain vulnerability that we all experienced and continue to experience. And to help this Committee, in my view, to develop legislation to help solve these problems for the future. I think we owe it to those who lost their lives during this pandemic and all the disruptions it has caused to get this right.*

*“We studied this issue because it became apparent that by the time the virus reached our shores, there was little we could do to prevent the shortages of critical supplies. The spike in demand for medical supplies was too high, the production of those supplies too far away, and too centralized in places hit hard by the virus. At the same time, the Strategic National Stockpile was underprepared. The roots of these issues extend far past December 31, 2019 when a cluster of cases was first reported in Wuhan, China.*

*“So what does this mean? Preparation for the pandemic should have begun years in advance, obviously. The constraints experienced by federal, state, and local agencies, as well as hospitals, responders, and frontline workers, is the result of a supply chain and preparedness culture that seems to have suffered a failure of imagination regarding those worst case scenarios.*

*“While many factors contributed to our poor state of medical supply preparedness—which we will discuss here today—the state of the Strategic National Stockpile is chief among them, and that’s our responsibility here in the federal government. The stockpile’s mandate has been to respond to discrete emergencies, not a simultaneous 50-state pandemic. And for more than a decade, the stockpile focused on local chemical, biological, radiological, and nuclear threats often at the expense of pandemic preparedness. It also did respond effectively during the H1N1 pandemic with millions of PPE items and antivirals, but those were confined outbreaks, and the stockpile was never replenished after that episode. In the intervening years, of course, the stockpile’s mission continued to be less of a pandemic response and the question is why?*

*“Compounding these preparation failures by the stockpile, the past two decades have seen a consistent off-shoring of medical supply manufacturing. We all know about that, and we’ll hear about that more today, particularly the U.S. relying on China for 75 percent of sanitary and hospital bed articles and 50 percent of our PPE, including N95 masks.*

*“Today, I look forward to hearing from our witnesses on three broad questions. First, what steps should the United States take to reduce overreliance on foreign countries for critical medical supplies? We need to understand how to diversify supply chains away from China, reshoring manufacturing to the United States, and incentivizing production in the Western Hemisphere.*

*“Second, how do we foster a strong ‘Industrial Commons’ for medical supplies in the United States? It’s a key part of our competitiveness going forward, I think. It’s where you have a manufacturer, you have suppliers, inventors, skilled workers, and distributors, all networked and integrated together. It’s not just about assembling gowns or pharmaceuticals, but about building out a supply chain that brings together the producers of the components of those items with the innovators also. These networks offer efficiencies, make it more difficult to offshore in the future, and increase innovation.*

*“Third, as we develop this effort for medical supplies, how do we ensure that we have the right supplies, in the right quantities, and effective distributions for the future crisis? I also am concerned about the inadequacies of the SNS, as we talked about – the stockpile. Going forward we need to properly define the role of that stockpile and be sure that it has the resources and capabilities we need to succeed.*

*“Thanks again to our witnesses for testifying today, I look forward to hearing your thoughts on the path forward. And, of course, look forward to continuing our approach to this, which I hope can remain nonpartisan and focused on actually how do you come up with solutions so that we can be more prepared in the future. Thank you.”*

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Testimony of

**Dr. Shereef Elnahal**

President & CEO

COVID-19 Part II:

Evaluating the Medical Supply Chain and Pandemic Response  
Gaps

United States Senate

Homeland Security &

Governmental Affairs Committee

May 19, 2021

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Chairman Peters, Ranking Member Portman, Members of the Committee on Homeland Security and Governmental Affairs, my fellow panelists.

My name is Dr. Shereef Elnahal, President and CEO of University Hospital in Newark, New Jersey.

I thank the Committee for the opportunity to offer insights into my institution's experiences during COVID-19, and to offer the institution's support for the Help Onshore Manufacturing Efficiencies for Drugs and Devices Act and the Pharmaceutical Accountability, Responsibility, and Transparency Act.

If they had been enacted prior to the pandemic, the PART and HOME Acts would have helped my hospital better meet the care needs of our community during a difficult time. And I believe they would help the country make great strides in building a more reliable, domestic-based supply chain for future health emergencies.

University Hospital is New Jersey's only state hospital, and one of only 962 state and local government-run community hospitals in the United States. We are the Level 1 Trauma Center for the densely-populated northern New Jersey region. We are an academic medical center, and the principal teaching hospital for all Newark-based medical education, including Rutgers New Jersey Medical School – a robust, preeminent training ground for the next generation of healthcare heroes.

Last year, we had more than 83,000 emergency room visits, admitted some 15,600 patients, and had 200,000 outpatient visits. As one of New Jersey's safety net hospitals, we serve as a critical healthcare provider for a large population of low-income and Black and Brown residents.

Due to our close proximity to Newark Liberty International Airport, we had been closely monitoring the progress of COVID-19 since early January 2020, when the CDC began screening passengers at major U.S. airports, including JFK International, just 31 miles away.

That said, we were completely unprepared to address the surge of patients that followed a few short weeks later.

In April 2020, at the peak of the first surge of COVID-19, we had 300 patients in house being treated for COVID-19.

For decades, our nation has struggled to appropriately focus on the strategic national stockpile of essential supplies and medication. While it is tempting to point fingers,

the fact of the matter is that the failure to maintain the country's strategic national stockpile was a long-term oversight that has spanned many decades.

COVID-19 brought with it things we have never seen before in healthcare – things we hopefully will never see again.

We found ourselves needing to react and pivot every single day to address the surge of patients that followed for weeks and months to come.

As the number of COVID cases in our emergency rooms and intensive care units doubled, tripled and quadrupled, we found ourselves at risk of running out of supplies for which we have never seen shortages before. This includes protective equipment for our staff, and ventilators for the patients with the most severe cases of COVID-19.

Suppliers serviced the highest bidders. Safety net hospitals, like University Hospital, were frequently the last to be called back.

Key medications, especially those which are used to sedate patients on ventilators, were also dangerously low. Failing to sedate someone on a ventilator is agonizing for the patient. As professionals dedicated to healing, this was an outcome that we refused to accept, and we worked around the clock on these issues to help patients survive COVID. No patient went without such medications, but we were days away from this outcome in the most critical times.

In many cases, we needed to find suppliers with whom we had no track record and who had little to no history serving the U.S. medical community. At the same time, we were keenly aware that fraud was happening from many angles across the country. Occasionally, we needed to return or discard deliveries when items purchased were discovered to be ineffective in protecting against infection.

Supply negotiations were a daily occurrence. Our suppliers were taking phone calls from us, along with hundreds of other hospitals and health systems – all of whom had the same urgent need for important medications and essential supplies. In many cases, we needed to find suppliers with whom we had no buying history.

As soon as a new therapy to treat COVID-19 would emerge, the drug would rapidly be ordered from the wholesaler and their existing inventory would disappear.

To manage the situation as best as possible given the supply limitations, we put together a pharmaceutical pandemic plan, as well as a critical list of alternatives to some of the more heavily used pharmaceuticals, in an effort to decrease the burden on our existing stock of critical medications.

Our hospital pharmacy leadership was in near constant contact with colleagues at other New Jersey healthcare institutions in an effort to assist each other. If there were drugs they could spare at a given time, especially when another institution was perilously low on stock, the spirit of cooperation would take over in the name of patient care.

By not making marked changes in the manufacture of medications here in the United States, and by not creating a strategic national stockpile of essential pharmaceuticals for the next public health emergency, the U.S. healthcare system will continue to be reliant on foreign manufacturers where critical medications are made, including China and India.

Domestically, without the ability to bolster domestic production and supply, we are at the mercy of these and other foreign trading partners. With foreign imports come competitive cost pressures on American suppliers. In effect, we have been subsidizing foreign manufacturers of equipment and supplies produced overseas, and during the pandemic, many of these nations stopped or delayed exports to their benefit, but to our detriment.

At University Hospital, we had a particular issue with ventilators. In mid-April we placed an order for 30 German-manufactured Dräger ventilators with an expected lead-time of 12 weeks. One month later, that lead-time had increased to 30 weeks. Although the firm denied it, the rumor in the industry was that the German government prevented their export. Eventually, we cancelled our Dräger order and placed an order for 35 additional Medtronic ventilators, expecting delivery of five units per week beginning the first week of May 2020.

Deliveries were timely early in the pandemic when cases were initially and largely limited to the New York, New Jersey, and only a few other regions nationally. However, supply deliveries slowed and even stopped when COVID-19 cases spiked in the South and Midwest. The last units were not delivered until January 2021 – much later than anticipated and significantly past the time they were needed to make the greatest impact.

These vital supply shortages illustrate a systemic, industry-wide issue. The things we needed the most were the exact same resources that all hospitals needed. So, every hospital was working their contacts across the global supply chain at the same time. This was compounded by businesses and individuals, outside the healthcare setting, taxing the supply chain even further as they attempted to purchase hospital-grade materials for their employees and families.

Our situation was dire – both within our hospital’s walls and on our financial balance sheets. Things were so grave that we briefly ran out of space in our hospital morgue, resorting to freezer trucks in a parking lot adjacent to the hospital. Regardless, each deceased patient was treated with the same dignity, care and respect as they received prior to their passing.

The CARES Act saved our hospital. Without funds that kept our hospital afloat during the worst of this, we projected that we would have found ourselves unable to make payroll by August of 2020. Hospitals simply cannot fail during a pandemic. If we had to close, it would have been a catastrophe in our community, on top of a pandemic.

Aside from the federal assistance, New Jersey’s state government – including Governor Phil Murphy – helped University Hospital receive a share of the national stockpile, including N-95 masks, gowns, ventilators and more. Without the CARES Act, University Hospital would have struggled in ways that some other hospitals had to just across the Hudson River, when some staff found themselves using trash bags as isolation gowns to provide patient care.

As a Level 1 trauma center, we were also the regional coordinator for hospital beds across New Jersey’s densely populated northern region during the acute surges. CARES Act funding was particularly helpful for this arduous task, which would not have been possible without federal government support.

Timing also played a key factor. We received federal and state aid at exactly the time we needed it the most. We ultimately used \$25 million in federal funds for PPE and other COVID-related purchases. These vital supplies were purchased for our own hospital, as well as the New Jersey emergency field hospitals that we coordinated and outfitted for the State of New Jersey.

We also received vital staffing support when we needed it most. The Department of Defense assigned 85 military healthcare providers to our hospital in April and May of 2020. These providers, part of the United States Army’s Urban Augmentation Medical Task Forces, embedded with our staff and helped us provide necessary relief to our overworked team members and those in our hospital family who turned into COVID-19 patients themselves.

And our important work did not stop with patient care. We were one of a few sites nationwide that conducted the Moderna vaccine trial in a majority-minority community. We were also the first hospital to administer a vaccine in New Jersey

outside of a clinical trial last December, and we continue to provide all three approved vaccines to our community.

We did many virtual town halls to reassure our community that they can trust the vaccine, helping to quell the justified mistrust in the healthcare establishment dating back to slavery and the horrors of the Tuskegee experiment, and acknowledging the implicit bias that people of color continue to face in health care settings. More and more people in the community we serve accepted the vaccine over time. Now, the challenge is access. We have re-routed our vaccination strategy in recent days to be where people are with mobile vaccination efforts in collaboration with our city, county, and state governments, and hope that more organizations will join us in this effort in the coming months.

Vaccine hesitancy persists, and we continue to work with our neighbors and community leaders to offer many virtual community forums, in-person health fairs, and community direct outreach to address the safety and efficacy of the vaccines.

Finally, our hospital continues to work diligently and intently to vaccinate the community. On a recent Saturday, for example, we vaccinated 338 people at a health and wellness festival. By the end of the week, we will have provided 39,000 vaccine injections and fully vaccinated 20,000 members of our community. A number of people were able to receive vaccines with no appointment needed.

Today, nearly 33 million Americans have been diagnosed with COVID-19. Nearly 600,000 have passed away. 35% of the entire population has been fully vaccinated.

Today, we are in the final miles of the pandemic, but our public health crisis isn't completely over. We need to repair the cracks in our national healthcare foundation, including the medical supply chain, while there is time.

The reality is that I am still not convinced that we are prepared for the next pandemic – whether from a vaccine-resistant variant of COVID-19 or a different pathogen altogether. While we are better off now as a result of many initiatives from the Biden administration on supply chain resiliency, there is still much work to do.

Maximizing the use of the authorities under the Defense Production Act has had a beneficial impact and has led to real changes for vaccine accessibility. One of the first Executive Orders President Biden signed after taking office dealt directly with the nation's supply chain, calling for a public health supply chain resilience plan among other, thoughtful efforts.

Still, there remains the matter of financial solvency for institutions like University Hospital during times of crisis like this. To continue depending on herculean, federal rescue efforts during these crises would indicate a failure to prepare. We need meaningful, value-based payment reform to this effect, sooner rather than later.

When the pandemic struck, there was never a higher demand for health care in American hospitals, and yet, the financial risk for hospitals and health systems was never higher. This fundamental disconnect between payment and value has existed for decades, and has forced hospitals with thin margins to use just-in-time inventory practices for these critical items. There was little incentive or capability to build stockpiles at the facility level, and we found that state and national stockpiles were also depleted.

We ultimately need a system of payment for care that does not rely on advanced medical procedures or elective surgeries for hospitals to remain afloat, but rather, allows the health care safety net to thrive by paying institutions for services that keep people healthy.

University Hospital has always been there for each and every person that seeks our care. We are honored and humbled to do so, and will always be there for our patients and the community.

In the meantime, we need to act now to ensure we are prepared for the next pandemic with the supplies, medication, and equipment we need to care for anyone who walks through our doors.

Thank you for the opportunity to provide our perspective, and I look forward to your questions.

**Written Statement of Robert B. Handfield, PhD, before the U.S. Senate Committee on Homeland Security and Governmental Affairs, May 19, 2021**

My name is Dr. Robert Handfield, and I currently serve as the Bank of America Distinguished University Professor of Supply Chain Management in the Poole College of Management at North Carolina State University, and Executive Director of the Supply Chain Resource Cooperative. I have studied purchasing and supply chain management for more than 30 years, and have a notable number of research publications in the field. I have also served as a supply chain consultant to more than 40 Fortune 100 companies, spanning the fields of healthcare, pharmaceuticals, industrial manufacturing, oil and gas, electronics, and have worked in government acquisition (including the VA, GSA, and DoD). I have also written several textbooks in purchasing which are used globally in academia.

In March 2020, a group of us in academia and government began working with the various national supply chain task forces responding to COVID-19. We were quickly met with the overwhelming realization that our country was not prepared to respond to the supply chain needs. Not only were we not prepared, but existing response structure had left us dependent on overseas supply chains that cut us off from much needed PPE and other medical supplies. During this period, the scarcity in critical supplies, medical and otherwise, resulted in a new tragedy of the commons. One in which the pasture being grazed is covered in human lives. Our recommendations for a renewed SNS were described in an [article in the Milbank Quarterly](#), and the [Harvard Business Review](#), both published in 2020.

In March 2020, I began volunteering my expert advice to the Department of the Air Force Acquisition Task Force, under the Department of Defense Joint Acquisition Task Force. One of my professional academic colleagues is an Active Duty Air Force officer who was completing his PhD at UNC Chapel Hill and was also asked to support the task force. He had asked for my advice during the initial emergency response. I continued to volunteer advice from March to June of 2020. During this time I provided advice and information regarding market intelligence and analysis for supply of PPE, N95 masks, gowns and gloves, ventilators, testing kits, and other key material. This task led me to have hundreds of Zoom calls with individuals in different federal agencies (DoD, FEMA, DHS, Strategic National Stockpile, DLA, GSA), state agencies (NASPO, GRA), private sector companies (manufacturers of pharmaceuticals, textiles, medical devices, distributors), universities and hospitals (UNC, WakeMed, National Hospital Association), as well as other subject matter experts. At the same time I began to receive similar requests for advice from a host of state agencies and private companies. My colleagues and I developed a presentation for SNS 2.0 made for the Principal Deputy Assistant Secretary of Defense for Logistics at OSD based on our research, expertise and observations during the initial response. Many of these recommendations are further developed in my testimony today.

In this response I have brought to bear industry knowledge and current experiences to develop insights into what happened, what went wrong, and how to fix it. I should also note that I wrote a [position paper](#) for the IBM Center for the Business of Government published in 2011 based on the SARS pandemic, titled "Planning for the Inevitable: The Role of the Federal Supply Chain in

Planning for National Emergencies". Many of the recommendations made in this report, if they had been followed, would have led to I believe a much better response to COVID. (I would be happy to help support your team, if there is an opportunity to do so on a subcontract basis.)

In this testimony today, I will begin by describing the state of the Strategic National Stockpile and the state of U.S. medical supply chain readiness prior to January 2020, including the longstanding reliance on foreign sources for critical drugs and medical supplies. I will then describe the events that occurred during January and February 2020, including the Defense Production Act, Strategic National Stockpile, and emergency contracting capabilities. I will also discuss federal roles and responsibilities during the initial response to COVID-19 related to preparation for, mitigation of, and coordination with states, hospital systems, and others to address anticipated medical supply shortages. I should also emphasize that this responsibility is not just that of the federal government; as [documented in our Harvard Business Review article](#) in 2021, all states, government agencies, and private sector companies need to be better prepared in the future. Finally, I will discuss needed reforms to strengthen U.S. medical supply chain vulnerabilities and better prepare for future public health emergencies, and the guiding principles for my vision of a renewed SNS 2.0.

Table 1 – Supply Shortages During COVID

Masks (Surgical and N95 respirator)	Belgians modified snorkeling masks <a href="https://www.medscape.com/viewarticle/927732">https://www.medscape.com/viewarticle/927732</a>
Goggles	Potential sources of PPEs: High school/University chemistry/biology/engineering labs – goggles, gloves, aprons. Oil fields and construction
Face Shields	
Gowns/Gloves, Shoe covers	Reach out to construction companies
Lab supplies (bread) test kits & reagents for them	
Isolation Stethoscopes	
Biohazard bags	
Sanitizers	Isopropanol & Ethanol suppliers:
Expiratory CO2 Detector	needed to help rapidly verify tracheal intubation
Laryngoscopes	Must have durable and disposable:
Macintosh Blades	size 2-4
Miller Blades	size 2-4
Glidescopes and Blades	necessary for very difficult intubations - 1 per hospital likely sufficient
Endotracheal (ET) Tubes	Sizes 6-8 (5 tubes) Prefer subglottic suction port to decrease Ventilator Associated Pneumonia (VAP)
ET Tube Securing devices	
Durable Cloth Medical Tape	Can be used as substitute for securing devices
Laryngeal Mask Airways	Necessary to support patients for short periods when intubation is very difficult
10 CC syringes	Necessary to inflate ET tube
Cuff Pressure Manometers	Necessary
bougie intubation tubes	necessary for very difficult intubations
nasal and oral airway devices	necessary to assure sufficient ventilation before intubation
Expiratory CO2 in-line sensor adaptors	
ECG Monitoring Contacts	
Pulse Oximetry devices (stickers and wearable devices for isolation)	
Suction Supplies	Necessary to maintain airways
Canisters	will require multiple with extended vent requirements
Tubing	
Endotracheal Suction Catheters	
Red Rubber Suction Catheters	
50 PSI O2 and Air Wall Adapters	
Tracheostomy Kits	
Ambu Bags/Masks	
Viral Expiratory Filters	necessary for both ventilators and ambu bags
PEEP Values: adjustable or 5/7.5/10 cmH2O	necessary for patients with Acute Respiratory Distress Syndrome (ARDS) when patient is off ventilator
Travel Ventilators	
Travel Vent Circuits	
Inline Nebulizer Adaptor and Small Volume Nebulizers	necessary to administer aerosolized medications
Heated Ventilator Circuits	prefer heated circuits to decrease incidence of VAP
Humidifiers	
Heat and Moisture Exchangers	prefer humidified circuit but necessary for transport and as substitute to humidifier
Patient Restraints	necessary to prevent involuntary extubation
18 and 22 mm adaptors	necessary to assure PEEP valve/TIME/In-line nebulizer compatibility
Bronchoscopy Kits	
Vaccine - Rapid Production	
Therapeutic Drugs - Rapid Production	
Furosemide	Medical community has found that diuretics are critical in treating COVID patients
Propofol	Necessary for sedation of intubated patients
succinylcholine	paralytic necessary for intubation procedure and to manage most critical vent patients
Midazolam	Necessary for sedation of intubated patients
Environmental	
Healthcare (BRT- RN- AMI)	
Quick Accreditation for ICU/Vent capability	
Bed and Associated facilities Supply	
Wheel chairs, mobile beds/stretchers	to move/transfer patients
IV fluids	
Oxygen cylinders	
Refrigerators/freezers for medications/samples and others	
Parts and/or access to 3D printers and raw materials to <a href="https://3dprintingindustry.com/">https://3dprintingindustry.com/</a>	
No-contact Infrared Thermometers calibrated for humans	
Refrigerated/cool chain trucks	in case of overwhelming cases of deaths
Food, beverages, water	Access to them - For healthcare workers
Dialysis machines, accessories and medications	
Anesthesia, CPAP/BIPAP machines that can be modified to <a href="https://www.fda.gov/media/1363">https://www.fda.gov/media/1363</a> if number of patients needing ventilators increase exponentially	
Manufacturing locations that can produce PPEs with no access to raw materials to produce if dearth of PPEs occur. Exports of PPEs (except probably only from China) are being restricted.	
Space: temporary testing/disinfection spaces outside the <a href="https://twitter.com/CNNsIRRoom">https://twitter.com/CNNsIRRoom</a>	
Self-swab test kits to be potentially launched this week	to be potentially launched this week Potential for overload of testing with self-swab test kits.
Batteries (as required) for equipments	

**What was the state of readiness of the Strategic National Stockpile and the U.S. medical supply chain prior to January 2020?**

As stated in my earlier report (Handfield, 2011) the U.S. medical system has been increasingly reliant on low cost manufacturing from overseas sources, a trend that has been occurring for the last thirty years. Much of this activity has been driven by the continued pressure of the

healthcare system to buy pharmaceutical products and medical supplies at the lowest cost. Medical supplies include many of the items shown in Table 1 below, which includes surgical and N95 masks, gowns, latex gloves, catheters, single use tubing, Propofol, IV fluids bioreactor bags, and many other items. All of the products shown in Table 1 experienced significant supply shortages during the COVID crisis. Beginning as early as the 1970s many companies moved their manufacturing to low-cost regions to gain improved labor cost—often one of the highest contributors to the cost of goods sold. Offshoring was enabled by international trade agreements struck between nation states, reductions in duties and taxes and other government incentives. The offshoring of production often meant that firms established large, centralized, production facilities to exploit volume advantages, in locations such as China and India. Final products were manufactured in centralized facilities and then shipped around the globe to large distribution centers in the US and Europe. Many of the distributors of these products, including companies like Cardinal, McKesson, Owens and Minor, Premier, MedAssets, and others, bought them in large quantities at discounts, and then sold them in bulk to hospitals, based on contracts that promoted a “stack ‘em higher, buy ‘em cheaper” mentality. This practice was also encouraged by increased pressure on hospitals by CMS and private insurance companies to reduce patient costs. For products like nitrile gloves, there emerged near monopolies like Top Glove and Viet Glove in Vietnam. For N95 masks, more than half of the world’s supply came from China, and in fact, much of that was produced in the Wuhan region where COVID originated! 3M also secured all of their raw materials for masks from China, and their factory there was directed to sell only within China by the government through April 2020.

In pharmaceuticals, as more common products became generic, many of the inputs for drugs, known as Active Pharmaceutical Ingredients were sourced from India, which then sources many of their materials from China. Manufacturing is outsourced to Contract Manufacturing Organizations (CMO’s) who are often evaluated based on a per unit price basis, and directed by brand pharmaceuticals to produce according to the “recipe” provided them using the suppliers they were directed to buy from.

There were inherent risks with buying low cost medical supplies and pharmaceuticals from Asia. First, there was a lack of direct control and oversight over operations, and the risk of GMP and quality problems was significantly higher. Second, most shipments were made by ocean freight, and the leadtimes for such shipments became longer and longer, as the ships became larger and slower and made more frequent stops (again to save money and drive down the cost of transportation). Distributors in the US tried to keep inventory as low as possible, and tried to keep as little safety stock on hand as possible. Domestic manufacturers of medical products could not compete with these low costs, and many went under or transferred operations to Asia. The Chinese tariffs created further problems as supply became constrained. One of the biggest risks overlooked was the remote possibility that export controls or product shortages would cut off our supplies of medical supplies, a risk which in fact came to fruition in early 2020. Another risk I observed during my work with hospital supply chains is that they often had very poor inventory management practices, with little visibility to their current inventory levels, which we referred to in our paper “Blurry Vision: Supply Chain Visibility for PPE during COVID”.

During my research, I also had an opportunity to speak at length with several members who worked in the Strategic National Stockpile, and who shared with me some key insights. A bit of history regarding the origin of the SNS is important to note here, and this testimony is in no way intended to be acrimonious in nature to the hard working men and women who staffed this agency during COVID. In fact, their diligence and long hours they put in to try to react to what was an untenable situation is duly noted, and my critiques here are limited to the design of the SNS, as opposed to a direct criticism of the people working within it.

Prior to COVID, the SNS was somewhat of a “secret” organization, as they did not publicize what they did. The genesis of the organization was on bioterror, not pandemics. The SNS was thus never designed or intended to be able to respond to a pandemic such as COVID. The majority of the people working within it were inventory logisticians, not supply chain logisticians. That means most individuals did not have experience managing warehouse and transportation and acquisition activities, but were rather focused on optimizing the stockpile of goods given very limited funding. The SNS managed about 800 product lines, and spent much of their time focused on how to spread out limited funds on acquiring materials to cover threats. Prior to COVID, potential threats were often determined by HHS to determine what to invest in, but this was a public health science view of potential scenarios that might arise, and had little to do with supplying demand for products. And scientists at HHS have a difficult time predicting things. Rather, they look forensically and medically at a problem, but are generally slow and not good at predicting what is needed and how to respond to a future need. In 2017, the composition of the SNS inventory was largely determined by the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which issued a strategic plan outlining the key areas for inventory investment.<sup>1</sup> PHEMCE is composed of multiple agencies who assess the current set of global threats. Number one on that list was \$5.7B for pandemic influenza, which included development of vaccines with BARDA, as well as replenishment of expiring material in the SNS. Unfortunately, this excellent plan was allowed to languish, and in 2018 was not restarted. This was tragic, as we would have been in a much better place if it had been carried out. For instance, the supply of N95 masks in the SNS consisted of inventory acquired during the 2009 SARS epidemic. Because these masks were acquired with one-time supplemental influenza funding, they were never replenished, and by the time COVID hit, most of them were expired and useless. In addition, \$2.3B had been allocated on anthrax vaccines that were never shown to be effective, for a threat that was never really validated, which dated back to 2004. So the ability to cover all 12 of the PHEMCE areas was not possible as funding for the SNS was cut back further. Its ability to source based on risk was largely determined by scientists, and even then, often involved one-time events, never for a persistent on-going pandemic like COVID.

The SNS had been part of the CDC for more than 10 years, and in the last two years, was transferred over to ASPR as part of the HHS. This was not really the right place for it to reside, as again it reported up to medical scientists, not emergency response agencies. Their leader Greg Burrell had retired in November 2019 and did not even have a deputy director assigned and was leaderless. The agency did not have enough warehouse capacity to procuring and storing

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<sup>1</sup> <https://www.phe.gov/Preparedness/mcm/phemce/phemce-myb/FY2018-2022/Pages/exec-summary.aspx>

materials, even if they had done so. And there was little precedence for them to store products and sell them into the market, as so much of their inventory went to waste and had to be given for free to the public in the event of an event. Having significant appropriations associated with disposal of expired goods was not an option.

Despite these problems, the SNS did have early indicators of a pandemic that was imminent in January 2020. On January 29, the SNS issued an Analysis of Logistics Summary (ALES), a new reporting mechanism it was piloting for the first time. The ALES asked for a response from key distributors, who all responded that they were all on allocation of PPE on February 1 from suppliers in China, and even noted that they had heard China was nationalizing product and they were experiencing an inability to get transportation to the ports for exports of these goods. By February 3, all of the distributors were being slammed with requests for PPE, which they did not have. One quote I recall is that “I was shocked at how many manufacturers and distributors have so little visibility into their tier 2, 3, and 4 suppliers.” Members of the SNS spoke leaders up the chain of command within the HHS, but again, these were scientists who did not understand how supply chains operated, and despite an SNS briefing predicting what would happen, they were not listened to. By March, when the DPA was enacted, it was much too late to obtain PPE and supplies, as distributors and manufacturers were unable to get products out of China. I also spoke to many state CPO’s who experienced the same issue, and some of them in fact had their shipments commandeered by HHS and FEMA later that summer at the ports.

**Table 2.** Organizations Consulted During COVID

<b>Government</b>	<b>Provider</b>	<b>Intermediaries</b>	<b>Other Industries</b>
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
FEMA DHHD 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 U.S. Sewn Products Industry
FEMA Initial “War Room” Team	Banner Health		North Carolina Healthcare Association

FEMA Tower Team	Montage Health		American Public Power
Joint DOD Healthcare Team			Beroe, Inc.
JAIC Project SALUS Team			Helena COVID-19 Network Project
			Resilinc
DOE			Exiger
CBRN Office FEMA			Govini
Biomedical Advanced Research and Development Authority (BARDA)			

#### Federal Roles and Responsibilities in Responding to COVID and Medical Shortages

During the COVID pandemic, the federal response suffered from a number of problems which we observed through discussions with personnel across a number of agencies shown in Table 2.

1. A singular lack of federal-level market intelligence and supply chain transparency left the government ill prepared. Because the SNS was never designed to anticipate every risk, it was forced to prepare for a wide variety of possible disruptions by mounting a response with little intelligence. To be better prepared, a multi-agency collaborative effort that relies on multiple sources of information is required. The Playbook for Early Response to High-Consequence Emerging Infectious Disease Threats and Biological Incidents describes a number of agencies that should be involved on the medical side, including DHS, DOT, NIH, CDC, ASPR, USAID, DOD, USDA, FDA and others.<sup>2</sup> But there also needs to be a supply chain facing organization, that is prepared to provide insights into categories of medical supplies and the state of those markets, that is responsible for developing acquisition and logistics strategies to ensure management of these items. 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.<sup>3</sup> 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.

<sup>2</sup> <https://www.prolific.com/qwiki.cgi?mode=previewSynd&uuiid=VAXM1WWF9J6RQ336F82Q7WSFK6QT>.

<sup>3</sup> Defense Pricing and Contracting. n.d. Contingency contracting.

<https://www.acq.osd.mil/dpap/pacc/cc/index.html>. Accessed September 3, 2020.10. Monczka R, Handfield R, Giunipero L, Patterson J. *Purchasing and Supply Chain Management*. 7th ed. Cincinnati, OH: Southwestern Publishing, College Division; 2019.

2. A lack of technology for material visibility within the SNS, FEMA, and state procurement offices led to a lack of demand insights and the inability to detect shortages in hospitals and the national stockpile. 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.<sup>4</sup> 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, and many of the masks were past their expiration dates.<sup>5</sup> We further discovered that significant shortages of PPE were not being reported publicly by the CDC during this period. A report by the **National Healthcare Safety Network (NHSN)** recorded on June 10, 2020, which is part of the CDC, is the nation's most widely used healthcare-associated infection tracking system, and reported that 40% of hospitals could not get N-95 masks.
  
3. The federal government'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. My discussions with state CPO's suggested that partnerships with private sector companies, such as the association between the state of Michigan and General Motors, facilitated access to Chinese suppliers through assets that were on the ground in Shanghai. Many distributors were unable to get supplies, and were inundated with promises from bogus suppliers in Asia that they could produce masks. They were also flooded with orders from hospitals, who were desperate and were placing orders with everyone, making it difficult to understand what the actual demand levels really were. Donald Trump's Executive Order 13909, which was issued on March 18, allowed the government to "determine...the proper nationwide priorities and allocation of all health and medical resources...for responding to the spread of COVID-19 within the United States." Project Airbridge was designed to airlift masks from China, but it was never revealed the actual number of masks and supplies that were acquired.
  
4. Disparate means of communication and coordination among public agencies were apparent to everyone. Today the Division of the Strategic National Stockpile occupies

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<sup>4</sup> US Government Accountability Office. VA acquisition management: supply chain management and COVID19 response. Report no. GAO-20-638T. Washington, DC; 2020.

<sup>5</sup> Bender M, Ballhaus R. How Trump sowed COVID supply chaos. "Try getting it yourselves." *Wall Street Journal*. August 31, 2020. [https://www.wsj.com/articles/how-trump-sowed-COVID-supply-chaos-try-getting-it-yourselves-11598893051#comments\\_sector](https://www.wsj.com/articles/how-trump-sowed-COVID-supply-chaos-try-getting-it-yourselves-11598893051#comments_sector). Accessed October 12, 2020.

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. A significant investment needs to be made in staffing the SNS with experienced supply management professionals, who are knowledgeable in developing category strategies for these materials. Many of these issues were problematic because of a lack of visibility technology, a lack of a barcoding system for track and trace of material locations, expiration dates, and consumption, and a lack of market intelligence on what was happening in the supply markets for these items.
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.<sup>24</sup> 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 random allocations is necessary for our national health care policy. Today, no such policy exists, as there has never been a situation comparable to COVID whereby every state in the country required emergency medical supplies.
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.

### Principles for a Renewed SNS 2.0

I will also lay out the principles for a what I believe is renewed SNS 2.0. In general, I believe the stated objectives the future state SNS has a strong appeal, but I believe there is an opportunity to influence this model in a more proactive and innovative manner. The ideas of having a control-tower to create real-time visibility to the current state of material in the stockpile is a good one, but there remains a number of challenges with respect to data governance, as well as the source of the data, for creating a control tower initiative. As described in my book [The LIVING Supply Chain](#), the challenge will be to ensure the right data is available to the right people at the right time to make decisions. However, my biggest concern is that the overall stockpile construct in its current form within ASPR does not recognize the realities of current global healthcare supply chains. I am a co-author on a paper that was published in the Milbank Quarterly, developed a full basis for how to govern the national federal pandemic response. I have additional research papers published in the Harvard Business Review and the [Journal of Purchasing and Supply Management](#) that also develops further insights on these issues.

The idea behind the SNS is not so much to focus on resiliency as the outcome, but rather to create a [supply chain that is immune](#) to shocks that may occur, including a wide variety of potential disruptions. A key component of a future state SNS is the ability to withstand different requirements that need to be pulled together on short notice. This requires advanced planning, effective category intelligence, and strategic sourcing plans for every key **need that might arise in an emergency**. The Pandemic Planning Team needs to develop demand sensing capabilities, war-gaming situations/simulations to inform category strategies, and capacity requirements that span both domestic and global sources. Requirements should embed industry standards to create maximum flexibility and increase alternatives in the event of need. This is the opposite of stockpiling of items, but rather involves contractual requirements and effective supplier development to ensure availability of supplies. We can begin with National Response Framework (NRF) items, and build on other requirements based on wargaming and simulations to assess what might be needed under different scenarios.

Increasing the stockpile size is simply going to create more waste. We advocate a “living” stockpile that covers and increases the number of sites. For instance, a number of DoD/VA Facilities carrying excess capacity can act as stockpile so long as they are tracked in real time. This requires enhanced data management to provide real-time view of material, and a FIFO inventory management approach to utilize stock that will minimize waste assuring fresh stock for the national stockpile, and minimize obsolescence. Private firms such as Amazon offer “buy and hold” inventory management options that could also be scaled to act as living stockpiles in addition to or in place of the DoD/VA clinic option. This approach would also utilize current sourcing research practices to ensure goods are state of the art, and aligned with the realities of the supply market situation, through focused category management and market intelligence.

We have to establish an SNS that is positioned with demand-sensing capabilities, that drive the people within the supply chain into action, to prepare and fight against the invader. And we need

to train our national supply chain system on how to prepare for this response. Supply chain immunity, in the case of massive disruptions of life-saving products and services, means the ability to survive, plain and simple. It is important, but many of us in the fight have noticed that the concept itself is not enough. We need the 'how', not just the 'what' in times of how to act in emergencies. We need to know how to prevent recent supply chain failures from reoccurring, should there be another pandemic or global event that affects all global supply chains. What we need is a [plan for ongoing and persistent immunity](#) for the SNS.

### **1. Emerging Technologies**

Contractual requirements must be supplemented by inventory visibility systems tied to a control tower, as well as blockchain (or other distributed ledger) 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. A missing component of the COVID response was the inability to track where products were coming from, where they were being sent, and who was receiving them. The hoarding that is occurring can be prevented by inventory visibility systems, that employ barcode and QR code tracking of material through the supply chain, through a trusted network of distributors and manufacturers. 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 vs. self-reporting demand that can contribute heavily to the tragedy of the commons scenario. This technology is not overly expensive (Handfield and Linton, 2017), but requires a centralized mandate and infrastructure to pull required data into a data lake that can serve as the single source of truth. This data lake must be curated carefully by a centralized group of information technology (IT) professionals, to ensure that data quality, reliability, and timeliness is not compromised. Traceability and transparency can reduce the risk of profiteering, counterfeiting and quality degradation in critical supply chains as well. We mandate that blockchain and visibility are critical features not a nice to have for the future strategic national stockpile (SNS) and should be used by all healthcare logistics functions.

### **2. How to create manufacturing surge capacity?**

Asking Manufacturers to reserve capacity/quantities of material to supplement the SNS is not going to happen. We now know we cannot rely on this strategy – foreign manufacturers will voluntarily or be forced to serve their country's needs first. Analysis I conducted with the S&P Market Intelligence shows how exports into the US were restricted during this period. Our manufacturers most often rely upon foreign supply chains, and this is not going to change overnight. Companies like 3M could not get masks delivered from This is simply not a workable proposition. Reserving manufacturing capacity is simply not possible, as most of the time this requires significant advance notice to scale up, and manufacturers do not have control over the capacity of their tier two suppliers in foreign countries. We are not going to be able to control manufacturing capacity which even if contractually reserved, and many of these products

unavailable to tap into during the COVID crisis (and remain so today) During any major global crisis, this will similarly be the case.

**3. What industries can be re-shored?**

There are problems with the idea of re-shoring manufacturing to the United States. My discussions with manufacturing executives suggest that once an organization commits to outsourcing to third parties in low-cost countries, there is a minimum planning horizon of five years involved, as this requires supplier qualification, audits, start-up, quality certification, and on-going ramp-up. In many industries, sourcing executives have embedded their supply chains in Asian regions, noting that “...these jobs will never return to Western countries.” As an example, 80% of the world’s production of certain medical products are produced by four manufacturers in one province in China. To establish alternative sources that are competitive, qualified, and at-scale would cost much more than the 25% in tariffs companies are paying today in the U.S. to import from China.

In my research I developed a framework of supply chain strategies for geopolitical risk mitigation (see Figure 1), which provides some guidelines to the federal supply chain on whether to adopt centralized/regionalized or localized supply chain designs according to how entrenched their suppliers are in a particular geographic location as well as how severe the geopolitical disruption is perceived to be.



**Figure 1: Framework for Supply Chain Strategies for Geopolitical Risk Mitigation**

The Y-axis of Figure 1 shows the shifts in the external business environment, which have rendered it difficult to localize or shift the supply base, because of the entrenched nature of the supply

base, or the cost-prohibitive elements for doing so. We note here that many Chinese industries were established with government investment, and the cost of capital for developing local sources is a significant barrier for investing in local supply capacity. The X-axis refers to the perceived likelihood of on-going political risk and disruption that is likely to continue, including the likelihood of on-going tariffs, customs duties, quotas, and export restrictions, resulting from a major and ongoing geopolitical event such as Brexit or the US-China trade war. In general, there are four strategies that emerge.

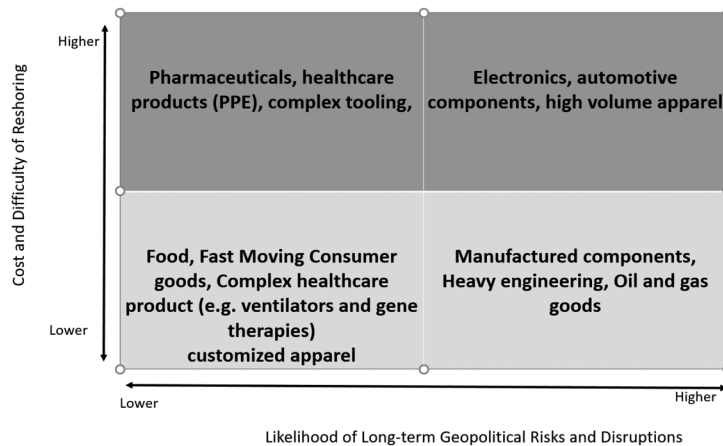
**Strategy 1: “Grin and Bear It”** - *High difficulty of reshoring, High likelihood of on-going geopolitical risk.* The increasing cost of moving products from an overseas supplier has been escalating, not just because of labor costs but also because of transportation costs, tariffs, duties, and supply discontinuity have dramatically increased the discussions around localization. This perception has escalated following the COVID-19 crisis, as borders were suddenly shut down for critical materials like PPE and ventilators. However, there are some economic factors that simply cannot be overcome, where entrenched supply bases produce a “Grin-and-Bear-It” approach. This approach recognizes that in some industries, supply chain redesign is difficult, if not impossible, such as in the electronics industry where the epicenter of component manufacturing and final assembly is in Asia. Under the “Grin-and-Bear-It” approach, we suggest companies will prioritize short-term tactical efforts such as building redundancies and holding inventory at different points in the supply chain. Other tactical strategies may include moving production to nearby locations (such as Vietnam) or transshipping through nearby locations to allow for a change in the country of origin customs label and the avoidance of tariffs.

**Strategy 2: “Explore Your Options”**- *Low difficulty of reshoring, High likelihood of on-going geopolitical risk.* The movement towards localization strategies is a function of the supply chain logics that prioritize the avoidance of uncertainty and risk, and an acknowledgment of the importance of lowering the total landed costs of goods, which occurs naturally as suppliers are located closer to customers. Localization is particularly relevant due to the size/cost ratio of goods with large, bulky, and low-margin items (such as food and beverages, vehicles, fabrications) being manufactured closer to the point of consumption because they are expensive to transport. There is also an opportunity to increase domestic sourcing to exploit local market knowledge and drive growth. Consider the case of mobile phone technology and how local producers in India and China have taken massive market share by moving towards regional supply chains that produce locally for local markets. Proximity drives lower costs by being closer to customers and closer to the point of sale. For the same reason, Amazon is opening Distribution Centers close to major centers of demand in the United States, with many US retailers moving to a same-day or next-day logistics delivery model.

**Strategy 3: “Tactical Warfare”**- *High difficulty of reshoring, Lower likelihood of on-going geopolitical risk.* For some products, such as pharmaceuticals, medical supplies, healthcare products, and complex tooling, we may see reduced tariff barriers as access to these products is deemed critical following the COVID crisis. For instance, we are unlikely to see a sudden surge of local production of high volume, low-cost medical products in Western economies. For products within this quadrant, the expectation is that geopolitical risks will not be ongoing, with such risks

not perceived as being not substantial enough to justify the cost of relocating production. Companies in this quadrant will adopt short-term tactical measures such as tariff avoidance, regional distribution centers with inventory, and national stockpiles of goods. However, if there is maintained political pressure for these types of goods to be produced locally, such as pharmaceuticals to treat the symptoms of COVID-19 or PPE, these industries will consider shifting production on-shore. In addition, we may see manufacturing, heavy engineering, and oil and gas seek to develop local suppliers of engineered products, to ensure business continuity and develop secondary sources of supply, even though costs may increase.

**Strategy 4: “Buy Local”** - *Low difficulty of reshoring, Low likelihood of on-going geopolitical risk.* For those products that are subject to local cultural differentiation and local sources of supply, we will see localized supply chain designs dominate, with this category expected to grow further as consumer demand for local products increases. Industries in this sector include food, especially fresh fruit, vegetables, and meat, as well as complex health products such as customized pharmaceutical products (gene therapies) and ventilators. For example, we are beginning to observe new start-up companies in areas such as customized apparel, who are seeking to develop digital apparel production capabilities in response to consumers who are seeking customized clothing and want it delivered within 48 hours, and localized capabilities will become important for this sector. We now map the industries in our study to the four strategies shown in Figure 1 to provide an indicative framework for supply chain designs (see Figure 2).



**Figure 2: Indicative mapping of supply chain risk mitigation strategies by industry**

**4. How to develop a flexible sourcing stockpile?**

We need to move away from the idea of simply increasing the Strategic National Stockpile, and think more in terms of the “Strategic National Sourcing” framework. What is needed is

a sophisticated approach for development of category strategies, combined with deep supply market intelligence around how to construct strategies to mitigate risk. “Supply market intelligence can be defined as a process for creating competitive advantage and reducing risk through increased knowledge of supply market dynamics and supply base composition.” (Handfield, 2010, p. 43)<sup>6</sup>. I use the term “supply” in this definition and construct label, but this idea applies directly to services as well (i.e., you can gain knowledge about the dynamics and composition of available service providers.). Market research, in a public context, is the collecting and analyzing of information about capabilities within the market to satisfy agency needs (Federal Acquisition Regulation, Subpart 2). This can consist of surveillance and investigation techniques. Surveillance is a continuous awareness process whereas investigation consists of targeted, comprehensive analysis for a direct need. We note that supply chains and markets can be viewed as having informational attributes that can be viewed in the aggregate or at discrete, finite levels. We can ‘zoom in’ or ‘zoom out’. It can also be viewed along a temporal dimensional attribute. Any future governance framework should consider these attributes and look for useful, analogous frameworks from which to learn.

##### 5. How to organize equitable distribution?

Fifth, asking distributors to warehouse goods and then be responsible for distribution is not feasible. I have written two books on pharmaceutical and healthcare distribution (Handfield, 2012; 2013)<sup>7</sup>, which have highlighted a number of structural issues with healthcare distribution that make it problematic for distributors to house finished goods inventory buffers or at point of care. One of the biggest challenges is the allocation of goods, which historically has been not equitable. During the COVID crisis, the SNS failed to serve a large number of healthcare institutions, namely smaller hospitals in less populated states. This was clear during many of the conversations I had with the National Association of State Procurement Officers as well as with the National Governors Association. Further, private distributors and GPO’s will always first serve their primary customers based on who has the greatest buying power and based on prior existing relationships, and there is thus a need for increased visibility and fair allocation mechanisms that are transparent to all. (Note that the CDC NHSN has the data to demonstrate that major shortages of PPE and masks were not equitably distributed.).

An equitable system for distribution is especially needed during an emergency, and a federal policy is needed. During a pandemic the demand for materials can come from many different

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<sup>6</sup> Handfield, R. (2010). Supply Market Intelligence: Think Differently, Gain an Edge. *Supply Chain Management Review*, 14(6), pp. 42-44, 46-49.

<sup>7</sup> Handfield, Robert, *Biopharmaceutical Supply Chains, Distribution, Regulatory, Systems, and Structural Changes Ahead*, Boca Raton, FL: Taylor & Francis, June, 2012.  
Handfield, Robert, *Patient-Focused Network Integration in BioPharma: Strategic Imperatives for the Years Ahead*, Boca Raton, FL: Taylor & Francis, June, 2013.

kinds of organizations. We have seen large integrated delivery systems, individual hospitals (in and outside of these systems), government delivery systems including military and VA, prisons, nursing and senior residential facilities and rural hospitals and clinics all seeking medical supplies. Importantly, all have had access or lack of access to different sources. The “alternative market” that emerged during COVID-19, consisting principally of suppliers with personal contacts in Asia that were not part of the every-day PPE production system, targeted many of these 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. To have an equitable system requires input from the various provider organizations regarding demand on their systems – but also focuses on preparedness (just in case) – which, if credible, may well prevent hoarding. If we can see where things are going, we can alleviate the need to rely on distributors and vendors to allocate material to the right places, whereas a demand sensing capability at the SNS level can drive allocation to the right states and counties most in need. Resource availability is key, but we note that information availability may be just as important, if not more so. We note that current COVID19 supply strategies have become a zero-sum game given asymmetric information, and new forms of governance are required to address these shortfalls.

#### **6. How to develop better market intelligence?**

Having capabilities and flexibility in sourcing alternatives is a key attribute for creating supply chain immunity for the federal supply chain. There are a number of components of an SNS that cannot be sourced domestically 100%, as it may not be practical or even possible. Outsourcing of manufacturing capabilities in North America has been on-going for more than 20 years. Even today, our experience is that many DoD contracts for aircraft and naval components are not commercially available in the United States, and are often obtained through local distributors sourcing to third party manufacturers overseas. The goal should therefore be to maintain domestic sources where it makes sense, to support national security, and create a global network of trusted suppliers who are willing to become part of the blockchain/visibility network. This may also involve partnering with organizations like Resilinc that monitor global events in supply markets and map these to key global suppliers. This can facilitate an understanding of the full risk picture, promote securing national needs first, with a “cold eye” on global impacts. Early warning is the key to early action, which can prevent shortages and capacity problems from occurring if one is too late to the game. The idea is not to remove global suppliers from the field, as this is not only impossible for certain categories of material, but may be detrimental to overall supply chain risk. We need to ensure that we cannot be removed either. This policy is not to be confused with base nationalism (which would be exclusion oriented/isolationist intent on keeping others out.). Rather the goal is to create a network of suppliers that can flex and collaborate through a trusted co-determined future relationship with a major government agency. Many global suppliers would love to be part of such a network. We have learned, during the COVID-19 epidemic, that organizations, across the globe, which were involved in manufacturing non-PPE materials, were quick to ramp-up their ability to produce PPEs. What they lacked was access to distribution systems for their products, leading to disorganized approach to making

an introduction to those hospitals and locations in need. A coordinated effort might have channeled these nouveau-suppliers to meet these contractual obligations over an extended period of time. Strategies that are focused on demand shaping with suppliers also has a major impact on cost and availability of supplies, much more so than typical “strategic sourcing” RFQ’s and evaluation of bids. These approaches will not function well in the case of managing the stockpile. We summarize these key actions in Table 2 below.

Table 2 – Actions

Objective	Key Result	Timeline
Complete traceability in SNS stock	Blockchain enablement across entire SNS	6-12 months
Increase SNS flexibility	DOD and VA hospitals become living stockpiles	12 months
Increase SNS durability	Reduce large lot buys and move to joint-purchased phased delivery	Waterfall based on existing supplier contracts
Utilize SNS Volumes to Enhance DPA	Multi-year purchases with all DPA/DPA-Like Vendors	2 months
Increase SNS global independence	Universities and labs funded for JIT development of critical need/fallback source material/items for SNS	5 years
Increase SNS flexibility	Develop/maintain strategic sourcing plans for every key need that might arise in an emergency	2 years

### **7. What are the skills and requirements for staffing the SNS 2.0?**

Understanding the supply market for critical items, and developing a sourcing strategy, including a risk mitigation strategy if there is an impending issue, is critical for on-going management of global events and keeping abreast of what is happening in each area. Category managers could be flow-through positions for MBA and other graduate students going through a supply management program, and could be updated on a bi-annual basis, affiliated with a major set of universities that have supply chain management programs.

Category intelligence can help establish built in triggers for preparing the SNS given early warning. There are perhaps two planning scenarios for action: generic material usage, and responsive/reactive mode. Example: should the SNS have been activated when Wuhan was "hot"? This is another argument for a "living stockpile" and persistent market intelligence in regards to having vendors with excess capacity – rapidly increasing stock would only be constrained by the carrying capacity of our government points of care. The vast majority of our defense bases have large storage facilities, even if not in the hospital itself, that could serve as stockpile locations. The risk with a warehouse stockpile is that we acquire a massive amount of goods that we waste, if they roll right into a hospital inventory they can be whittled away over time. The issue with the current use of massive contracts with large buys (in addition to the fact that the goods go stale at the same time) is that rapidly pulsing the base for more at any moment is not possible.

### **8. How will federal contracting change?**

I believe that alternative contracting approaches are required to deploy a the new SNS model. First, legislation is required to ensure that DEA Level I and II pharmaceuticals have daily reporting and visibility at the SNS locations. Second, there needs to be a policy to enable mass deployment of agreements with suppliers that are simple, and identify terms such as price, delivery, and leadtimes. These should be contracted early with multiple alternative suppliers, to provide a number of different sources for different elements of PPE. Suppliers should be qualified and audited prior to agreements, to ensure they are vetted against appropriate standards such as FDA, NIOSH, and others. I also suggest that different contractual arrangements should vary based on the category of product being sourced.

Our team considered how to best prioritize task forces requirements based on approval lead times and need levels that we think would hold well for a strategic national sourcing prioritizing framework. As shown below, supplies and services should fall into one of four quadrants defined by Source Approval Lead Time (SALT) - High and Low, and Source to Need (S2N) Ratio – High and Low. SALT includes both the time to vet new sources or new materials or service personnel themselves. This became especially important during a global health emergency where products must be vetted for safety and vendors must be vetted quickly to ensure they are not simply nonqualified opportunists.

Level 1 Requirements - low S2N ratio, high SALT bar. These offers should be reviewed by a team after a detailed vetting of the firm providing the offer (i.e., we would quickly look at alternatives from a reputable supplier, but set aside unknown, overseas or broker offers unless absolutely necessary).

Level 2 Requirements – low S2N ratio, low SALT bar. Vet quickly and set up agreement quickly. Distribute these to ready-to-go execution supplies or less specialized buying offices for mass acquisition. Consider pushing these to execution offices for vetting including open source market intelligence from commercial sources like Public Spend Forum’s GovShop or public information sources such as GSA Advantage.

Level 3 Requirements - high S2N ratio, high SALT bar. Establish a wave approval process. Vet sources in waves, place vetted sources on contract and plan to continuously review future sources as backups (i.e. primacy sources that are domestic and approved, secondary sources from partner nations, tertiary sourcing from export/import restricted countries as needed). Push these approval/reviews and oversight of reputable sources to execution with high levels of quality assurance and long-term oversight horizons.

Level 4 Requirements - high S2N ratio, low SALT bar. Simply let execution offices field these sources. As they come in in directly send these sources to buying offices. Don't worry about strategically sourcing these items, but require suppliers to report capacity and stock to ensure they don't slip into Level 2 requirements. Inform execution offices that they need to report incidences of stock-outs.

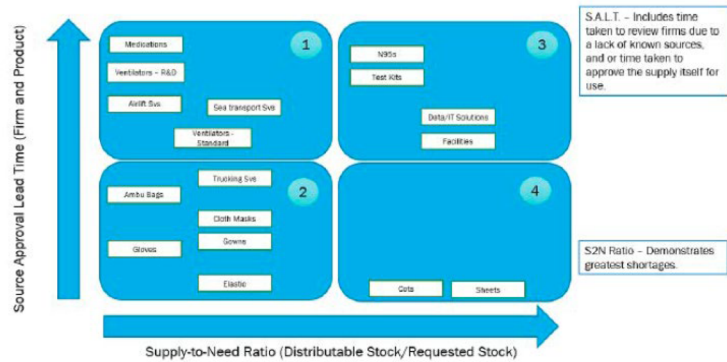


Figure Source: Finkenstadt D., “DAF ACT DASHBOARD ALT 1” developed 5 May 2020

**Conclusions:**

The idea behind the SNS is not so much to focus on resiliency as the outcome, but rather to create a [supply chain that is immune](#) to shocks that may occur, including a wide variety of potential disruptions. A key component of a future state SNS is the ability to withstand different requirements that need to be pulled together on short notice. This requires advanced planning, effective category intelligence, and strategic sourcing plans for every key **need that might arise in an emergency**.

We need the 'how', not just the 'what' in times of emergency. We need to know how to prevent recent supply chain failures from reoccurring, should there be another pandemic or global event that affects every global supply chain. What we need is a [plan for ongoing and persistent immunity](#) for the SNS.

The SNS 2.0 model we've proposed is a significant departure from previous versions of this agency. Globalization of supply chains and the reality of healthcare supply chain models will require a bold and innovative strategy for supporting our national response to pandemics, which I believe are likely to happen again. I have attempted to outline the problem and a set of possible solutions, and would be willing to support any efforts that move this forward.

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Statement on

**Strategic Assessment of the Resilience of the U.S. Drug Supply with  
Lessons from the Pandemic & Recommendations for Moving Beyond**

at the Senate Hearing on

**COVID-19 Part II: Evaluating the Medical Supply Chain and  
Pandemic Response Gaps**

Statement before the

**Committee on Homeland Security and Governmental Affairs  
United States Senate  
Congress of the United States**

Wednesday, May 19, 2021, at 2:30 p.m.  
Dirksen Senate Office Building, Room SD-342 and  
via videoconference.

Statement of

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Thank you Chairman Peters, Ranking Member Portman, and other members of the Senate Committee on Homeland Security and Government Affairs for this opportunity to provide information and insights from a “Strategic Assessment of the Resilience of the U.S. Drug Supply with Lessons from the Pandemic and Recommendations for Moving Beyond.”

I am Stephen W. Schondelmeyer, Professor of Pharmaceutical Management & Economics at the University of Minnesota where I serve as Co-Principal Investigator for the Resilient Drug Supply Project in the Center for Infectious Disease Research and Policy (CIDRAP). In addition, I am Director of the *PRIME* Institute which focuses on research and policy issues related to the pharmaceutical market and its impact on society. These remarks are my own views based upon my research and experience in studying the pharmaceutical marketplace for over forty-five years. Thank you for the opportunity to testify at this hearing. Previously, I have had the opportunity to interact with many of the federal entities that shape and influence our nation’s healthcare system including the Department of Health and Human Services and many of its divisions such as FDA, CMS, ASPE, ASPR, BARDA and with other federal agencies such as the FTC, GAO, and OMB.

This hearing on the state of drug and medical supply chains, both before and during the COVID-19 pandemic, is very timely. We can examine “How could we have been better prepared to face the challenges that a global pandemic has placed on our healthcare system?” We can evaluate the nation’s response to the pandemic as it unfolded and any vulnerabilities that were exposed in the supply chains that we depend upon for the very health and viability of this nation and its people. And, we can look for lessons learned or opportunities to improve the infrastructure of our medical supply chains so that they will be strong, resilient and effective at meeting the public health needs of our society in the face of future pandemics or other serious threats and challenges.

#### **State of the Drug Supply Chain Prior to the Pandemic**

First, let me ask a rhetorical question of everyone here. Is there anyone who has never been sick a day in their life? Is there anyone who has never needed or taken a prescription medication in their lifetime? It is hard to imagine someone living in America today who has not needed, taken, or benefited from the valuable medications that we have available today in modern medicine. In other words, there is a universal demand for prescription drugs—virtually everyone needs prescription drugs at some point in their life. The availability of, and access to critical medications is a necessity—not merely a consumer preference or a luxury good. Access to prescription drugs is a foundational component of an effective healthcare system.

Americans have come to count on critical and essential medications for serious and life-threatening diseases such as diabetes, chronic heart disease, asthma, epilepsy, and cancer. We expect that these essential medications will be available at the local hospital or at a nearby community pharmacy when they are needed. However, drug shortages have been, and still are, “a serious and recurring problem resulting from a web of factors rooted in an opaque drug production and drug supply chain, underfunded and underperforming government agencies, and a drug purchasing and distribution system with product allocation practices that are often secretive, unknown, and at times counterproductive.”<sup>1</sup> Drug shortages have been attributed to a variety of factors including unexpected demand surges; manufacturing difficulties; quality problems and recalls; supply and logistic disruptions; low prices for older, well-established generic drugs due to ‘over-competition’; market manipulation by various stakeholders; and other factors.<sup>2</sup>

For more than two decades, there has been a substantial number of drug shortages in the U.S. market.<sup>3,4</sup> Both the FDA and the American Society of Health System Pharmacists (ASHP) track and report on drug shortages.<sup>5,6</sup> ASHP reports that there have been more than 170 drugs in shortage at any point in time since 2014. Many of these drugs in shortage are essential or critical medicines that mean life or death to a specific patient. The drugs in short supply are often older, well-established medications that are generically available at a relatively low cost and many of the shortages have been for sterile injectables.

For some reason, the market has failed to support a sustainable presence and availability of these drugs. While economists would say that “in the long-run these market conditions will resolve themselves”, to the patient who needs a life-saving drug in the next few hours or days, very serious consequences—or even death—are virtually certain in the short-run. For example, vincristine—a life-saving drug for certain pediatric cancer patients—was in severe shortage late in 2019.<sup>7,8</sup> For the children who needed

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<sup>1</sup> Schondelmeyer S, Siefert J, Margraf D, et al. COVID-19: The CIDRAP Viewpoint, Part 6: Ensuring a Resilient US Prescription Drug Supply, October 21, 2020, available on the Resilient Drug Supply Project website at: <https://www.cidrap.umn.edu/rds> or directly at: <https://www.cidrap.umn.edu/sites/default/files/public/downloads/cidrap-covid19-viewpoint-part6.pdf>

<sup>2</sup> FDA. Drug Shortages: Root Causes and Potential Solutions. Report. Oct 2019.

<sup>3</sup> FDA. Drug Shortages, Oct 2019.

<sup>4</sup> Fox ER, Birt A, James KB, et al. ASHP guidelines on managing drug product shortages in hospitals and health systems. *Am J Health Syst Pharm* 2009 Aug 1;66 (15):1399-406; and, ASHP website: <https://www.ashp.org/Drug-Shortages/Current-Shortages>.

<sup>5</sup> FDA reported drug shortages can be found at: <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>

<sup>6</sup> ASHP reported drug shortages can be found at: <https://www.ashp.org/Drug-Shortages/Current-Shortages>

<sup>7</sup> Nelson R, ‘Complete Disruption’ of Supply of Essential Pediatric Chemo, *Medscape*, Oct 18, 2019; or, <https://www.medscape.com/viewarticle/920039>

<sup>8</sup> American Childhood Cancer Organization, The Vincristine Drug Shortage: A Medical Crisis for Childhood Cancer Families, November 23, 2019, available at: <https://www.acco.org/blog/the-vincristine-drug-shortage-update/>

vincristine at that time, they suffered because the drug was not there, at any cost, when they needed it.

*The drug shortage situation, even before the pandemic, was in need of a policy re-set. First, many appear to have accepted that drug shortages are an endemic problem that will always be with us and there is not much that we can, or should, do about them. They acknowledge that we can track drug shortages and work to resolve them after they have happened. This 'fail and fix' framework does have some value, but it means society will have an ongoing residual of drugs in short supply and patients who cannot get the critical life-saving medications that they need. Instead, we should adopt a paradigm that assumes that elimination of all drug shortages is possible. This new approach should focus on a 'predict and prevent' paradigm.*

Second, *the current definitions of drug shortages are useful, but they lead to an underestimation of the scope, magnitude and cost of drug shortages.*<sup>9,10</sup> For example, FDA defines a drug shortage as "A period of time when the demand or projected demand for the drug within the U.S. exceeds its supply."<sup>11</sup> This definition is useful, but incomplete because it characterizes a drug shortage as a market-wide economic problem, but does not recognize the impact of drug shortages on individual patients. ASHP defines a drug shortage as "A supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent."<sup>12</sup> This definition is also useful, but it frames drug shortages primarily as a supply and work flow issue. We need to develop a new more comprehensive definition of drug shortages that recognizes drug shortages as a continuum. Certainly when no one in the market has access to a needed drug there is a shortage, but also when even one patient does not have a critical and needed drug that patient has a drug shortage. *A needed drug that one does not have is neither safe nor effective.*

Two changes in the policy framework are urgently needed: (1) drug shortages should be viewed as a critical situation in which the total number of drug shortages can be substantially reduced or even eliminated; and (2) drug shortages should be re-defined to acknowledge that drug shortages exist along a continuum for just one patient who does not have the drug to a point where no patients have the drug. When even one patient who does not have a drug that is needed, it constitutes a drug shortage; and, we need to develop metrics to quantify and estimate the impact of all such drug shortages.

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<sup>9</sup> Institute for Safe Medication Practices. Drug shortages continue to compromise patient care. Jan 11, 2018.

<sup>10</sup> Shaban H, Maurer C, Willborn RJ. Impact of drug shortages on patient safety and pharmacy operation costs. *Fed Pract* 2018 Jan;35 (1):24-31.

<sup>11</sup> FDA. Drug Shortages. Oct 2019.

<sup>12</sup> Fox ER, et al. ASHP guidelines. *Am J Health Syst Pharm* 2009 Aug 1;66 (15):1399-406.

### **Impact of the Pandemic on the Drug Supply Chain**

The COVID-19 pandemic has had a monumental impact on the daily life of people around the world. The medical and drug supply chains have not escaped this global impact. The drug supply chain experienced a triple play during the first year of the pandemic: (1) increased demand, (2) disrupted and decreased supply, and (3) exposure of systemic vulnerabilities.

#### **Increased Demand**

Covid-19 caused demand surges due to a rise in infected cases that impacted various geographic regions quite differently and at different times. COVID-19 tends to strike hard in a discrete geographic area, and when it creates a new hot spot, the hospitals in that area usually see a dramatic spike in demand for admissions and ventilator use. In addition, use of certain critical COVID-19 drugs, such as azithromycin, may more than double overnight, while other drugs may see even steeper jumps of 5-fold (i.e., midazolam), 10-fold (i.e., cisatracurium), 20-fold (i.e., hydroxychloroquine) or even 40-fold (i.e., tocilizumab). Such explosive growth in critical acute drug use was seen in March and April of 2020 when the number of hospitalizations and critical care COVID-19 patients in New York and New Jersey skyrocketed. In part, the geographic and timing differences of surges helped mitigate some of the impact. If all states would have had the same kind of surge as New York and New Jersey, at the same time, the U.S. would have had more shortages of medical and drug supplies and those shortages would have been much more severe.

As the number of COVID-19 cases grew the healthcare system was stressed by increased hospital admissions, ICU care, ventilator usage, and deaths. Shortages were experienced with various products and services such as personal protective equipment like masks and gowns or with medical devices such as ventilators. Some hospitals adapted to the expected increase in COVID-19 hospitalizations by delaying or cancelling elective surgeries during April and May of 2020. While this adjustment in hospitalizations did help keep hospital and ICU beds open for COVID patients, and it reduced the demand for drugs such as the paralytics and sedatives used by patients receiving ventilation, those patients whose surgeries were delayed did experience the downstream ripple effect of postponed or foregone healthcare. Public health experts need to sort out the role and impact of various actions such as diagnostic testing, mask-wearing, social distancing, isolation and lockdowns, mandates, and other mitigation strategies.

The demand side for drugs saw dramatic U.S. and worldwide increases in certain therapies for COVID-19. Shortages of critical drugs used in treating COVID-19 patients have included propofol, albuterol, midazolam, hydroxychloroquine, cisatracurium, rocuronium, fentanyl, azithromycin, vancomycin, and others. In fact, among 40 critical

COVID-19 drugs identified by the Resilient Drug Supply Project (RDSP) (see Appendix A), 70% of them (28 of 40) were in short supply as recently as the end of January 2021 according to the ASHP drug shortage list.<sup>13</sup> The US FDA, with more stringent criteria for declaring a shortage, showed 40% (16 of 40) of the RDSP critical COVID-19 drugs in shortage at the same time.<sup>14</sup> Both of these drug shortage rates are unacceptable whether in times of a pandemic or not.

Oxygen is another medical supply that experienced increased demand and, in some cases, extreme shortages. Oxygen has a very unique production and distribution system that is different from the traditional drug distribution and supply market. There are many producers and suppliers in regional and local markets, as opposed to a few large producers serving a national market for traditional pharmaceuticals. There are about 36,000 firms registered with the FDA as oxygen manufacturers with businesses located in all 50 states as well as the District of Columbia and the U.S. territories.

### **Disrupted and Decreased Supply**

COVID-19 jolted the global pharmaceutical market at all levels and production points. The supply side was disrupted by factory closures, shipping delays or shutdowns, and trade limitations or export bans. As described in an overview<sup>15</sup> (see Appendix B) of the impact of the pandemic on the drug supply market, we saw stay-at-home orders and factory lockdowns in China,<sup>16</sup> followed by shipping port slowdowns and shutdowns.<sup>17</sup> Hubei province (and Wuhan city) in China alone had 37 pharmaceutical factories that held Drug Master Files for making active pharmaceutical ingredients (APIs) for US drug products.<sup>18,19</sup> Drugs made in the Hubei region include ibuprofen, hydromorphone, metoprolol, metformin, zidovudine, azithromycin, clindamycin, and levofloxacin.

Meanwhile, many Indian drug makers who rely heavily (about 70%) on China for key starting materials like benzene, as well as APIs, experienced delays in receiving the ingredients to make finished generic drug products for the global market.<sup>20</sup> In early March 2020, the Indian government was so concerned about having enough critical drugs to meet the needs of the Indian market that it restricted the export of 26 APIs and

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<sup>13</sup> ASHP. Current Drug Shortages: Drug Shortages and Management, <https://www.ashp.org/Drug-Shortages/Current-Shortages>.

<sup>14</sup> FDA. FDA Drug Shortages, <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.

<sup>15</sup> Schondelmeyer et al. Ensuring a Resilient US Prescription Drug Supply, October 21, 2020.

<sup>16</sup> Yap CW. China's factories struggle to resume operations after coronavirus shutdown. Wall Street Journal. Feb 8, 2020.

<sup>17</sup> Saul J, Baertlein L. China's coronavirus disrupts global container shipping trade. Reuters. Feb 6, 2020.

<sup>18</sup> Schurder G. Hubei vs. COVID-19: an in-depth focus on expected pharmaceutical supply chain disruptions & drug shortages, Supply Chain Channel. Mar 3, 2020.

<sup>19</sup> FDA. FDA Resources for Data Standards: Business Operations.

<sup>20</sup> Chandna H. India to curb export of antibiotics, vitamins as coronavirus crisis hits supplies from China. The Print. Feb 20, 2020.

finished drug products to prevent shortages in India.<sup>21</sup> The drugs on India's export ban list accounted for about 10% of India's total pharmaceutical exports and included acetaminophen, metronidazole, erythromycin, clindamycin, and several essential vitamins.<sup>22</sup> India later prohibited the export of hydroxychloroquine because domestic stocks were running low and it wanted to first fulfill its own requirements.<sup>23</sup> Other countries imposed trade limitations or export bans on pharmaceuticals, including the United Kingdom, which issued a ban on parallel export of 82 drugs, including insulin, amoxicillin, and acetaminophen.<sup>24</sup> China hinted in March (2020) that it might impose export controls on shipments of life-saving drugs to the US market, though it did not take that step.<sup>25</sup> This threat is particularly concerning because of China's dominance in the antibiotic market. China makes "nearly all" supplies of penicillin G and about 80% of the world's supply of many antibiotics.<sup>26</sup>

Many European Union (EU) countries and the United States looked to Italy as an alternate source of antibiotics when their supplies from China and India were disrupted. Italy was the EU's largest producer of antibiotics in 2018, accounting for 34% of the total EU consumption.<sup>27</sup> Italy, however, was hit early and hard by COVID-19 cases,<sup>28,29</sup> and, by early March, it had stopped all commercial activity (including drug factories) except for retail pharmacies and super markets, disrupting this alternate source.<sup>30</sup> By mid-March, most major European countries, including Spain, France, Germany, Switzerland, England, the Netherlands, Norway, Denmark, and Ireland, were severely affected by the pandemic.<sup>31</sup> Keep in mind that, in 2018, 19 of the top 20 brand name drug products in the United States were made overseas, mostly in Europe.<sup>32</sup>

### **Drug Supply Chain Vulnerabilities Exposed by the Pandemic**

The pandemic has exposed many of the vulnerabilities in the US drug supply chain. Among the vulnerabilities of the U.S. drug supply chain are: (1) heavy dependence upon foreign sources for drug production; (2) old factories, equipment and out-dated

<sup>21</sup> PTI, BloombergQuint. India restricts drug exports as threat of coronavirus rises. Mar 3, 2020.

<sup>22</sup> PTI, BloombergQuint. India restricts drug exports as threat of coronavirus rises. Mar 3, 2020.

<sup>23</sup> Ghangurde A. India bars exports of hydroxychloroquine with some exceptions. Pink Sheet. Mar 25, 2020.

<sup>24</sup> Wallace D. UK blocks 82 from parallel export. Generics Bulletin, Mar 20, 2020.

<sup>25</sup> Chakraborty B. China hints at denying Americans life-saving coronavirus drugs. Fox News, Mar 19, 2020.

<sup>26</sup> Harris G, Palmer AW. China has near-total control of the world's antibiotic supply. Is America at risk as a result? STAT, Apr 28, 2020.

<sup>27</sup> Eurostat. EU production and trade of antibiotics. Nov 18, 2019

<sup>28</sup> Amante A, Balmer C. Coronavirus outbreak grows in northern Italy, 16 cases reported in one day. Reuters. Feb 21, 2020.

<sup>29</sup> Coronavirus. Colpite tutte le regioni. La Protezione civile: ecco i numeri aggiornati (in Italian). Mar 5, 2020.

<sup>30</sup> Sylvers E, Legorano G. Italy hardens nationwide quarantine. Wall Street Journal. Mar 11, 2020.

<sup>31</sup> Henely J, Jones S. Do not let this fire burn: WHO warns Europe over COVID-19. The Guardian. Mar 13, 2020.

<sup>32</sup> Roos R. Experts say COVID-19 will likely lead to US drug shortages. CIDRAP News. Mar 27, 2020.

manufacturing processes; (3) chronic quality problems in certain sectors (i.e., sterile injectables); (4) challenges with inspection and quality control in foreign manufacturing facilities; (5) a shift from in-house manufacturing to a general contractor model of drug production; (6) geographic and economic concentration in certain markets; (7) lack of visibility into the upstream market by policymakers and key stakeholders; (8) a focus on just-in-time inventory control rather than surge management with slack resources for resilience; (9) misaligned regulatory and economic incentives in the pharmaceutical market; and (10) lack of a coordinated policy approach to the pharmaceutical market at the national level.

While emergence of the COVID-19 pandemic in early 2020 severely stressed the US drug supply chain, on balance the drug supply chain showed considerable overall strength and resilience.<sup>33,34</sup> However, many of the vulnerabilities of the drug supply chain need to be improved to avoid future consequences from challenges to the drug supply chain.

### **The Resilient Drug Supply Project**

The University of Minnesota's Center for Infectious Disease Research and Policy (CIDRAP) embarked on a Resilient Drug Supply Project (RDSP) in October 2018.<sup>35</sup> The mission of the RDSP is "to focus on the global supply chain for each prescription drug used in the U.S. healthcare market in order to reduce or avoid drug shortages due to increased demand or disruptions from any cause and for any reason." The RDSP has 8 broad and ambitious goals (see Appendix C) including: (1) define critical acute drugs; (2) define critical chronic drugs; (3) assess the consequences of drug shortages; (4) map the entire U.S. drug supply chain; (5) develop a model, or models, to predict drug shortages; (6) use predictive modeling and other methods to prevent drug shortages; (7) develop response plans to mitigate challenges to the drug supply and to manage drug shortages that do occur; and (8) evaluate and understand future trends expected in the pharmaceutical market to develop and facilitate policy directions that will reduce or eliminate drug shortages.

One of the first tasks for the RDSP was development of a list of Critical Acute Drugs. We used an expert panel process to define this term. Critical Acute Drugs were defined as: "Drugs that when medically needed in acute care must be available and used within hours or days of the need or the patient will suffer serious outcomes which may include

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<sup>33</sup> Healthcare Distribution Alliance, Rising to the Challenge: How Distributors Are Supporting a Resilient Pharmaceutical Supply Chain During COVID-19., 2021; available at: <https://healthdelivered.org/wp-content/uploads/2021/01/Rising-to-the-Challenge.pdf>.

<sup>34</sup> Healthcare Distribution Alliance, The First 90 Days: US Biopharmaceutical Finished Goods Supply Chain Response to COVID-19, 2020.

<sup>35</sup> This RDSP project has been generously funded by a member of the Walton Family Foundation.

disability or death." Absence of a Critical Acute Drug, or lack of availability of an effective substitute, may also cause serious health outcomes or limited ability to provide humane care." A total of 156 drug molecules were designated as Critical Acute Drugs. These 156 drug molecules account for nearly 20,000 actively marketed drug products (at the NDC level<sup>36</sup>) in the U.S. market.

The 156 Critical Acute Drugs were compared against the FDA and ASHP drug shortages list to determine how many of these critical drugs were in shortage. We found that 38.5% of them (60 of 156) were in short supply as recently as the end of January 2021 according to the ASHP drug shortage list.<sup>37</sup> The US FDA, with their more stringent criteria for declaring a shortage, showed 24.4% (38 of 156) of the RDSP critical acute drugs were in shortage at the same time.<sup>38</sup> Both of these drug shortage rates are unacceptable whether in times of a pandemic or not.

The RDSP is using publicly available data from FDA and various commercial sources to map the supply chain for each unique drug product identified in the market. We have started by mapping the NDCs for the 156 critical acute drugs. In particular, we are focusing on the upstream drug supply map because it is the source of many issues that lead to drug shortages, yet it is the most opaque part of the supply chain.

The diagram in Figure 1 below illustrates a simplified version of the drug supply chain. Basically, the dividing point for upstream and downstream is the point at which a drug product has been approved by the FDA for marketing, assigned an NDC number, and is physically in the U.S. and ready for shipment to wholesalers, pharmacies, or other qualified purchasers. While there are some issues in the downstream supply chain that may result in shortages, most drug shortages are the result of things that happen in the upstream supply chain such as quality issues, shipping delays, raw material shortages, geopolitical and economic issues, and other factors.

While most stakeholders know quite a lot about the downstream flow of prescription products, they know very little about the upstream market. If a food-borne infection event occurs, the CDC and FDA can track the food supply back to the farm where the food was grown and harvested. Most imported food products bear the country of origin on the consumer label so that the consumer can weigh the risks and value of food products from other markets in the world. For a pharmaceutical product there is usually one company name on the label, but that company is typically only the marketer or distributor and not the actual manufacturer who made and prepared the drug product.

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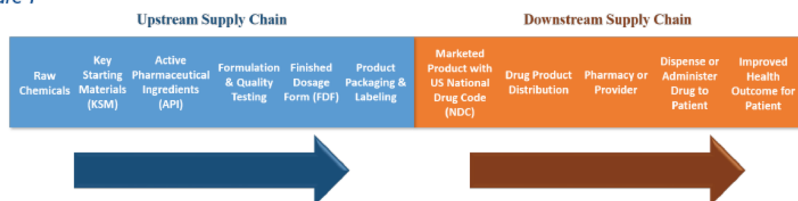
<sup>36</sup> The National Drug Code (NDC) is a unique code given to each drug product similar to the bar code used on items one would purchase at a store. Each unique NDC code specifies a certain drug molecule, dosage form, strength, package size and type and manufacturer or marketer.

<sup>37</sup> ASHP. Current Drug Shortages: Drug Shortages and Management, <https://www.ashp.org/Drug-Shortages/Current-Shortages>.

<sup>38</sup> FDA. FDA Drug Shortages, <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.

Furthermore, the label rarely discloses where the active ingredient was formulated or where the final dosage form of the drug product was prepared. One should ask why don't drug products bear 'country of origin' labeling like food, clothing, appliances, automobiles, and many other consumer goods.

Figure 1



### Findings from Mapping the Upstream Drug Supply Chain

Once the RDSP began building the upstream supply map for drug products, we began to look at the patterns based on country of origin for the active pharmaceutical ingredient (API) and the finished dosage form (FDF). Data for our mapping process have come from many sources including the FDA structured product labeling data set and Daily Med profiles, drug product labeling images, FDA NDC listing, FDA approved drugs, the FDA Orange Book and other FDA sources. Although the FDA has a lot of information on specific drug products and much of it is made public through the FDA web site, the information disclosed is not always complete, it is sometimes disjointed and the data across different files often cannot be combined or linked due to inadequate identifiers. Other data sources include shipping data, import-export records, commercial prescription utilization and pricing databases, and pharmaceutical trade and news sources. Selected findings from the RDSP are shown in Appendix D.

First, we examined 30 of the top brand name drugs in the U.S. market. Here is what we found:

- All of the FDA sponsors for these 30 brand name drugs appeared to be U.S. based companies, although many were U.S. subsidiaries of foreign parent companies;
- All, or nearly all, of the marketers and distributors appeared to be U.S. based companies or U.S. subsidiaries of foreign parent companies;
- From the downstream perspective nearly all of the drug products in the U.S. market appeared to be U.S. products;
- When we looked upstream only 20% (6 of 30) NDCs were finished drug products made in the United States; and, 4 of those 6 were made in Puerto Rico;
- 80% of the finished brand name drug products were made outside of the U.S.;

- Further upstream, only 10% (3 of 30) brand name drug products had API that was made in the U.S. while 90% (27 of 30) were made in foreign countries;
- The foreign countries where the top brand name drugs were made were nearly all in Europe with the exception of one product made in Mexico.

Next, we examined 30 of the top generic drugs in the U.S. market. This time we found:

- All of the FDA sponsors for these 30 generic drugs appeared to be U.S. based companies, although many were U.S. subsidiaries of foreign parent companies;
- All, or nearly all, of the generic marketers and distributors appeared to be U.S. based companies or U.S. subsidiaries of foreign parent companies;
- From the downstream perspective nearly all of the generic drug products in the U.S. market appeared to be U.S. products;
- When we looked upstream 80% (24 of 30) generic NDCs had finished drug products with foreign or unknown sources;
- Further upstream, 90% (27 of 30) generic drug products had API that was from foreign or unknown sources, while only 10% (3 of 30) were made in the U.S.;
- The foreign countries where the top generic drugs were made were nearly all in from India with 4 from Canada.

We examined one of the Critical Acute Drugs (Atracurium injection) and found that:

- Atracurium comes from 5 different sources with each source producing 2 NDCs.
- The downstream marketers and distributors all appear to be U.S. based companies or U.S. subsidiaries of foreign companies.
- These appear to be U.S. made drug products based on the downstream information.
- 2 of the NDCs were packed and labeled in India and the other 8 NDCs were from a source of unknown origin.
- The finished dosage form for 4 of the 10 NDCs were made in China and another 4 of the 10 NDCs were made in India, while 2 NDCs were from a source of unknown origin.
- The source of the active pharmaceutical ingredient was not disclosed for any of the 10 NDCs.

**Critical Acute Drug (CA 005): Atracurium Besylate**  
**Resilient Drug Supply Project, CIDRAP, University of Minnesota**

Critical Drug #	CA005	CA005	CA005	CA005	CA005	CA005	CA005	CA005	CA005	CA005
NDC #	00409-180	00409-180	25021-0809	25021-0822	55160-0516	55160-0219	70388-0701	70388-0702	67457-0699	67457-0699
Product	Atra-cu-rium	Atra-cu-rium	Atra-cu-rium	Atra-cu-rium	Atra-cu-rium	Atra-cu-rium	Atra-cu-rium	Atra-cu-rium	Atra-cu-rium	Atra-cu-rium
Drug Firm	Hospira, Inc.	Hospira, Inc.	Sagent Pharmaceuticals	Sagent Pharmaceuticals	AuroMedica Pharma LLC	AuroMedica Pharma LLC	Mylan Pharmaceuticals Inc.	Mylan Pharmaceuticals Inc.	Mylan Pharmaceuticals Inc.	Mylan Pharmaceuticals Inc.
Up Stream Supply Chain	Key Starting Materials	NR	NR	NR	NR	NR	NR	NR	NR	NR
	API Manufacture	NR	NR	NR	NR	NR	NR	NR	NR	NR
	Finished Drug Manufacture	India	India	China	China	India	India	China	China	NR
	Pack & Label Pack & Label	India	India	NR	NR	NR	NR	NR	NR	NR
Down Stream Supply Chain	FDA Sponsor (BIA   NDA   ANDA)	USA	USA	USA	USA	USA	USA	USA	USA	USA
		ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA
	Manufactured for:	USA	USA	USA	USA	USA	USA	USA	USA	USA
	Marketed by:	USA	USA	USA	USA	USA	USA	USA	USA	USA
	Distributed by:	USA	USA	USA	USA	USA	USA	USA	USA	USA
	Wholesale & GP Stock	USA	USA	USA	USA	USA	USA	USA	USA	USA
Pharmacy Stock	USA	USA	USA	USA	USA	USA	USA	USA	USA	
Patient	USA	USA	USA	USA	USA	USA	USA	USA	USA	

- USA
- USA-Puerto Rico
- No. America (Mexico & Canada)
- Europe
- Asia
- India
- Not Reported

Overall, we found that the top prescribed, and used, U.S. drug products, both brand and generic, are heavily dependent upon foreign sources for both the finished dosage form and the active pharmaceutical ingredients.

While production of pharmaceuticals in foreign countries is not necessarily a bad thing, there are several forces that raise questions about the level of dependence on foreign sources for the U.S. drug supply. Historically, the FDA has not been able to inspect foreign based plants with either the frequency or the candor that has been used when inspecting U.S. plants. There may be more concerns with quality in foreign-based plants that do not have the same level of regulatory oversight. Second, when drug products are coming from other countries there are more opportunities for logistical and shipping delays, as well as product damage in transit. Third, our dependence on other countries can provide those countries with opportunities for political and economic leverage on the United States. Depending upon the philosophy, ethics, and politics of other countries who grow to be in a dominant position for certain drug categories, the United States could find itself held hostage economically or politically over essential drugs.

This data showing that we are heavily dependent upon foreign sources for our domestic prescription drug supply. The re-shoring of some pharmaceutical production may be beneficial economically and logistically. However, we must also remember that diverse geographic locations for supply may be more resilient if specific events affect a certain

geographic region such as Hurricane Maria that devastated Puerto Rico in 2017 and disrupted the flow of large volume parenterals in the United States.

#### **Recommendations for Moving the Drug Supply Chain Beyond the Pandemic**

***The United States should have a process and infrastructure for analyzing, predicting, managing, and preventing shortages of critical medications.*** Currently, the U.S. does not have a coordinated effort to establish market-wide policy for the pharmaceutical market even though pharmaceuticals account for about 4% of the entire economy. While the FDA does have authority for regulating the safety and effectiveness of drug therapy, it does not have authority to assess or act on economic or market-based factors. The FDA does engage in substantial effort related to managing drug shortages. However, other government agencies often do not have access to the FDA data for operational or policy analysis. This fact became clear early in the pandemic as multiple federal and state agencies were scrambling to find information on the drug supply, how to anticipate what was ahead, and how to manage it to best mitigate drug shortages. To be fair, there was, and is, no silver bullet that could have quickly and easily protected the U.S. drug supply chain once the pandemic emerged. However, the ability to share drug-related data across federal agencies such as FDA, HHS, DHS, FEMA, BARDA, ASPE, ASPR, VA, TRICARE, and others could have been made more clear and could have been clearly authorized by Congress.

***An in-depth map of the U.S. drug supply is needed*** and should be maintained on an ongoing basis to facilitate planning for, and management of, market distorting events such as pandemics, weather events, man-made disasters, political and hostile threats and other situations that may arise.

***Congress should authorize and fund a national entity*** to: (1) build and maintain the U.S. drug supply map; (2) make the drug supply chain more transparent and the quality of drug products more visible; and (3) coordinate development of relevant national policy to reduce and eliminate drug shortages and to strengthen and improve the resilience of the U.S. drug supply as it faces future threats of all kinds. This national effort could be either a new entity or a re-tasking of an existing entity. The United States Pharmacopeial Convention is an independent, scientific and non-profit entity with a 200 year history of collaborating with government and the private market to improve the quality of drug therapy and outcomes. This history provides USP with a unique and intriguing position that could coordinate a public-private effort to address elimination and reduction of drug shortages. If a new entity was to be created, Congress may establish a new NIH National Institute for Pharmaceutical Resilience or it could create a quasi-governmental body such as the Prescription Drug Policy Review Commission in a manner similar and parallel to the Medicare Payment Advisory Commission (MedPAC). If an existing agency is to be tasked with this new focus, the possible candidates would

include the National Institutes of Health (NIH), the Food & Drug Administration (FDA), or the National Library of Medicine.

***Establish an ongoing research program on resilience of the US drug supply chain*** to include, but not be limited to: (1) development of a sentinel system that can predict and prevent supply chain disruptions; (2) reduce or eliminate drug shortages; and (3) coordinate a national response to drug shortages if they do happen.

In summary, drug shortages were here before the pandemic and they will still be here as we move beyond the pandemic. The efforts to track and mitigate drug shortages over the past decade have had a marginal impact, but drug shortages have not been substantially reduced in recent years, and drug product quality concerns are precipitating more widespread drug recalls (e.g., valsartan, ranitidine, and metformin). Continuing the status quo may threaten our confidence in the quality of prescription drugs and their availability. Obviously, we need to shift from a “fail and fix” framework to a “predict and prevent” paradigm. Implementing the recommendations in this report will provide a new national entity focused on better understanding the complex reasons for drug shortages and will establish a systematic approach for analyzing, predicting, preventing, and mitigating drug shortages. With the support of policymakers and cooperation of the FDA, other federal entities, and industry stakeholders, the U.S. pharmaceutical market can significantly reduce or eliminate drug shortages. Only then can we ensure a resilient supply of needed medications for the American population.

**Appendix A**

Resilient Drug Supply Project:  
Critical Acute Drug List & Critical COVID-19 Drug List  
Drug Shortages Reported by ASHP & FDA  
Shortages as of  
5-9-2021

**Resilient Drug Supply Project:  
Critical Acute Drug List & Critical COVID-19 Drug List  
Drug Shortages Reported by ASHP & FDA**

Drug #	Critical Acute Drugs Generic Name	Drug Category	UMN RDSP	UMN RDSP	Shortages as of 5/9/2021	
			List of 156 Critical Acute Drugs	List of 40 Critical COVID-19 Drugs	ASHP Drug Shortage List	FDA Drug Shortage List
1	Cisatracurium	Paralytic	X	X	Yes	Yes
2	Rocuronium	Paralytic	X	X	Yes	Yes
3	Vecuronium	Paralytic	X	X	Yes	Yes
4	Succinylcholine	Paralytic	X	X		
5	Atracurium	Paralytic	X			
6	Propofol	Sedation	X	X	Yes	Yes
7	Midazolam	Sedation	X	X	Yes	Yes
8	Lorazepam	Sedation	X	X	Yes	Yes
9	Dexmedetomidine	Sedation/Anesthesia	X	X	Yes	Yes
10	Phenobarbital	Sedation	X			
11	Ketamine	Sedation/Anesthesia	X	X	Yes	Yes
12	Diazepam	Sedation	X			
13	Lidocaine	Local Anesthetic	X		Yes	Yes
14	Bupivacaine	Local Anesthetic	X		Yes	Yes
15	Fentanyl	Pain	X	X	Yes	Yes
16	Hydromorphone	Pain	X	X	Yes	Yes
17	Morphine	Pain	X	X	Yes	Yes
18	Oxycodone	Pain	X	X		
19	Acetaminophen	Pain & Fever	X			
20	Ketorolac	Pain	X		Yes	Yes
21	Anakinra	Pain	X			
22	Oxygen	Medical Gas	X	X		
23	Nitric Oxide	Medical Gas	X			
24	Sevoflurane	Medical Gas	X			
25	Albuterol	Bronchodilator	X	X	Yes	
26	Ipratropium (Inhaler)	Bronchodilator	X			
27	Azithromycin	Anti-infective	X	X	Yes	Yes
28	Piperacillin-Tazobactam	Anti-infective	X	X		
29	Cefepime	Anti-infective	X	X	Yes	
30	Ceftriaxone	Anti-infective	X			
31	Vancomycin	Anti-infective	X	X	Yes	
32	Doxycycline	Anti-infective	X			
33	Meropenem	Anti-infective	X	X		
34	Cefazolin	Anti-infective	X	X	Yes	Yes
35	Levofloxacin	Anti-infective	X			
36	Linezolid	Anti-infective	X			
37	Ampicillin-Sulbactam	Anti-infective	X		Yes	
38	Sulfamethoxazole-Trimethoprim	Anti-infective	X			
39	Ceftazidime	Anti-infective	X	X	Yes	
40	Ciprofloxacin	Anti-infective	X			
41	Clindamycin	Anti-infective	X		Yes	
42	Gentamicin	Anti-infective	X		Yes	
43	Imipenem	Anti-infective	X			
44	Metronidazole	Anti-infective	X			
45	Ampicillin	Anti-infective	X			
46	Nafcillin	Anti-infective	X			
47	Oxacillin	Anti-infective	X			
48	Penicillin G	Anti-infective	X			
49	Tobramycin	Anti-infective	X			
50	Amphotericin B	Anti-infective	X			
51	Posaconazole	Antifungal	X			

Drug #	Critical Acute Drugs Generic Name	Drug Category	UMN RDSP List of 156 Critical Acute Drugs	UMN RDSP List of 40 Critical COVID-19 Drugs	ASHP Drug Shortage List	FDA Drug Shortage List
52	Ganciclovir (IV)	Antiviral	X			
53	Highly Active Anti-Retroviral Therapies**	Antiviral	X			
54	Hydroxychloroquine	Antiviral (Lupus, RA)	X	X	Yes	
55	Chlorhexidine	Antiseptic	X	X		
56	Betadine	Antiseptic	X			
57	Ethanol	Antiseptic	X			
58	Norepinephrine	Vasopressor	X	X	Yes	
59	Epinephrine	Vasopressor	X	X	Yes	Yes
60	Vasopressin	Vasopressor	X	X		
61	Phenylephrine	Vasopressor	X			
62	Amiodarone	Cardiovascular	X	X	Yes	
63	Hydralazine	Cardiovascular	X		Yes	Yes
64	Nicardipine	Cardiovascular	X			
65	Labetalol	Cardiovascular	X		Yes	
66	Metoprolol	Cardiovascular	X		Yes	
67	Esmolol	Cardiovascular	X			
68	Verapamil	Cardiovascular	X		Yes	
69	Diltiazem	Cardiovascular	X		Yes	Yes
70	Atropine	Cardiovascular	X		Yes	Yes
71	Adenosine	Cardiovascular	X			
72	Epoprostenol	Pulmonary Vasodilator	X			
73	Bosentan	Pulmonary Vasodilator	X			
74	Milrinone	Pulmonary Vasodilator	X			
75	Dexamethasone	Corticosteroids	X		Yes	Yes
76	Methylprednisolone	Corticosteroids	X			
77	Hydrocortisone	Corticosteroids	X		Yes	Yes
78	Betamethasone	Corticosteroids	X		Yes	
79	Prednisone	Corticosteroids	X		Yes	
80	Furosemide	Diuretic	X		Yes	Yes
81	Potassium chloride (IV)	Electrolyte Replacement	X			
82	Magnesium (IV)	Electrolyte Replacement	X		Yes	
83	Calcium chloride	Electrolyte Replacement	X	X		
84	Calcium gluconate	Electrolyte Replacement	X		Yes	Yes
85	Calcium carbonate	Electrolyte Replacement	X			
86	Sevelamer carbonate	Electrolyte Replacement	X			
87	Sodium bicarbonate	Electrolyte Replacement	X		Yes	Yes
88	Phosphorus	Electrolyte Replacement	X			
89	Zinc	Electrolyte Replacement	X			Yes
90	Sodium chloride (0.9%, 3%, 5% )	Electrolyte & Fluids	X		Yes	Yes
91	Lactated Ringers	Electrolyte & Fluids	X			
92	Dextrose (50%)	Electrolyte & Fluids	X			
93	Anticoagulant Citrate Dextrose Solution A	Electrolyte & Fluids	X			
94	Hemodialysis, Intermittent (IHD) Solution	Electrolyte & Fluids	X			
95	Peritoneal Dialysis (PD) Solution	Electrolyte & Fluids	X			
96	Renal Replacement Therapy, Continuous (CRRT)	Electrolyte & Fluids	X			Yes
97	Organ Preservation Solution	Electrolyte & Fluids	X			
98	Enoxaparin	Anticoagulant	X	X	Yes	
99	Heparin	Anticoagulant	X	X	Yes	Yes
100	Argatroban	Anticoagulant	X	X	Yes	
101	Tissue Plasminogen Activator (TPA)	Anticoagulant	X			
102	Warfarin	Anticoagulant	X			
103	Prothrombin complex conc. (Kcentra)	Warfarin Reversal	X			
104	Vitamin K (phytonadione)	Warfarin Reversal	X			
105	Insulin, Short acting- Regular (aspart)	Insulin & Endocrine	X			
106	Insulin, Long acting (Lantus, NPH)	Insulin & Endocrine	X			

Drug #	Critical Acute Drugs Generic Name	Drug Category	UMN RDSP List of 156 Critical Acute Drugs	UMN RDSP List of 40 Critical COVID-19 Drugs	ASHP Drug Shortage List	FDA Drug Shortage List
107	Desmopressin Acetate (DDAVP)	Insulin & Endocrine	X		Yes	Yes
108	Glucagon	Insulin & Endocrine	X			
109	Valproate sodium	Anti-epileptic	X		Yes	Yes
110	Carbamazepine	Anti-epileptic	X			
111	Fosphenytoin	Anti-epileptic	X			
112	Levetiracetam	Anti-epileptic	X		Yes	
113	Phenytoin	Anti-epileptic	X		Yes	
114	Antivenom, Snake (CroFab)	Antidote	X			
115	Antivenom, Spider	Antidote	X			
116	Dantrolene	Antidote	X			
117	Diphenhydramine	Antidote	X			
118	Epinephrine (EpiPen, auto-injector)	Antidote	X		Yes	Yes
119	Levocarnitine	Antidote	X			
120	Lipid emulsion (IV)	Antidote	X			
121	Methylene Blue	Antidote	X			
122	N-acetylcysteine	Antidote	X		Yes	
123	Naloxone	Antidote	X			
124	Neostigmine	Antidote	X			
125	Protamine	Antidote	X		Yes	Yes
126	Rabies Vaccine IG	Antidote	X			
127	Sugammadex	Antidote	X			
128	Tetanus toxoid	Antidote	X			
129	Vitamin B12 (hydroxocobalamin)	Antidote	X		Yes	Yes
130	Immune globulin (IV)	Immunodeficiency	X		Yes	
131	Epoetin	Blood Modifier	X			
132	Granulocyte-Colony Stimulating Factor (G-CSF)	Blood Modifier	X			
133	Granulocyte-Macrophage Colony- Stimulating Factor	Blood Modifier	X			
134	NPEG-Granulocyte-Colony Stimulating Factor (NPEG-G-CSF)	Blood Modifier	X			
135	Blood Factor IX	Hemophilia	X			
136	Blood Factor VII	Hemophilia	X			
137	Blood Factor VIII	Hemophilia	X			
138	Anti-inhibitor coagulant complex (FEIBA)	Hemophilia	X			
139	Tranexamic Acid	Hemophilia	X			
140	Mycophenolate Mofetil (MMF)	Immunosuppressant	X		Yes	
141	Tacrolimus	Immunosuppressant	X		Yes	Yes
142	Cyclophosphamide (CHOP regimen)	Lymphoma / Leukemia	X			
143	Doxorubicin (CHOP regimen)	Lymphoma / Leukemia	X		Yes	
144	Mechlorethamine (MOPP regimen)	Lymphoma / Leukemia	X			
145	Procarbazine (MOPP regimen)	Lymphoma / Leukemia	X			
146	Vincristine (CHOP, MOPP regimen)	Lymphoma / Leukemia	X			
147	Ondansetron (oral & inj)	Anti-emetics	X		Yes	Yes
148	Prochlorperazine	Anti-emetics	X		Yes	
149	Metoclopramide	Anti-emetics	X			
150	Methylergonovine	Pregnancy-related Medication	X			
151	Oxytocin	Pregnancy-related Medication	X			Yes
152	Surfactants	Pregnancy-related Medication	X			
153	Terbutaline	Pregnancy-related Medication	X			
154	Fluoxetine	Anti-psychotic	X			
155	Haloperidol	Anti-psychotic	X		Yes	
156	Olanzapine	Anti-psychotic	X			

Drug #	Critical Acute Drugs Generic Name	Drug Category	UMN RDSP	UMN RDSP	ASHP	FDA
			List of 156 Critical Acute Drugs	List of 40 Critical COVID-19 Drugs	Drug Shortage List	Drug Shortage List
Additional Critical Drugs for Treatment of COVID-19 Patients						
C1	Remdesivir*	Other Critical COVID-19 Drugs		X	Yes	Yes
C2	Lopinavir-Ritonavir	Other Critical COVID-19 Drugs		X		
C3	Oseltamivir	Other Critical COVID-19 Drugs		X		
C4	Chloroquine	Other Critical COVID-19 Drugs		X	Yes	
C5	Droperidol	Other Critical COVID-19 Drugs		X	Yes	
C6	Etomidate	Other Critical COVID-19 Drugs		X		
C7	Fluconazole	Other Critical COVID-19 Drugs		X		
C8	Vitamin C	Other Critical COVID-19 Drugs		X		
<b># of Drugs on Critical List</b>			156	40		
<b># of Drugs in Shortage (ASHP)</b>			60	27	63	
<b>% of Drugs in Shortage (ASHP)</b>			38.5%	67.5%		
<b># of Drugs in Shortage (FDA)</b>			36	15		37
<b>% of Drugs in Shortage (FDA)</b>			23.1%	37.5%		

**Resilient Drug Supply Project (RDSP)**

The Resilient Drug Supply Project is a research program of the University of Minnesota's CIDRAP and the PRIME Institute. The RDSP has been funded by a generous gift from the Walton Family Foundation

**UMN RDSP List of 156 Critical Acute Drugs**

**Critical Acute Drugs** are drugs that "when medically needed in acute care must be available and used within hours or days of the need or the patient will suffer serious health outcomes which may include disability or death. Absence of a Critical Acute Drug, or lack of availability of an effective substitute, may cause serious health outcomes or limited ability to provide humane care."

**Source of Critical Acute Drug List:** Created by an expert panel convened by the Univ. of Minnesota's RDSP on December 11 & 12, 2018.

Participating experts came from government, academia, and the private sector and represented the fields of pharmacy, medicine, nursing, public health, others in clinical health care, pharmaceutical supply chains, emergency preparedness and response, emergency medical services, and drug distribution.

**UMN RDSP List of 40 Critical COVID-19 Drugs**

**Critical COVID-19 Drugs:** drugs used in the active treatment of COVID-19 positive patients or their COVID-19 related symptoms.

**Source of Critical COVID-19 Drug List:** Created by the Univ. of Minnesota's Resilient Drug Supply Project staff in January of 2020.

"X" means that a drug is on the list named at the top of the column.

"Yes" means that a drug is on the active shortage list named at the top of the column (either ASHP or FDA).

\* Remdesivir (Gilead) has been approved by the FDA for treatment of COVID-19 requiring hospitalization in adults and pediatric patients age 12 and older.

\*\* Highly Active Anti-Retroviral Therapies (HAART) and particularly agents used for post-exposure prophylaxis (PEP) are included on the critical acute drug list.

( ) Information in parentheses after a drug name indicates a specific dosage form, strength or product name that is of interest on the Critical List.

**ASHP Drug Shortage List:** Drug shortages reported by the American Society of Health Systems can be found at:

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortages-List?page=CurrentShortages&loginreturnUrl=SSOCheckOnly>

**FDA Drug Shortage List:** Drug shortages reported by the U.S. Food & Drug Administration can be found at:

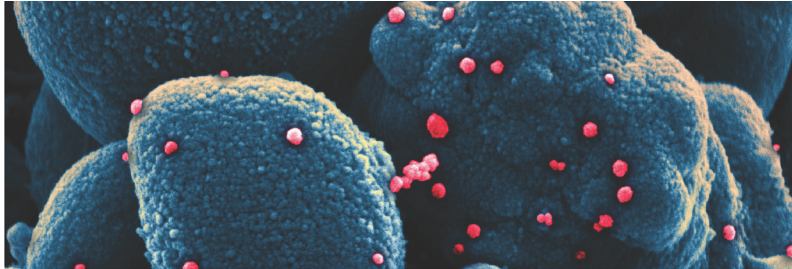
<https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>

**Appendix B**

Viewpoint, Part 6: Ensuring a Resilient US Prescription Drug Supply,  
October 21, 2020,  
Schondelmeyer S, Siefert J, Margraf D, et al,

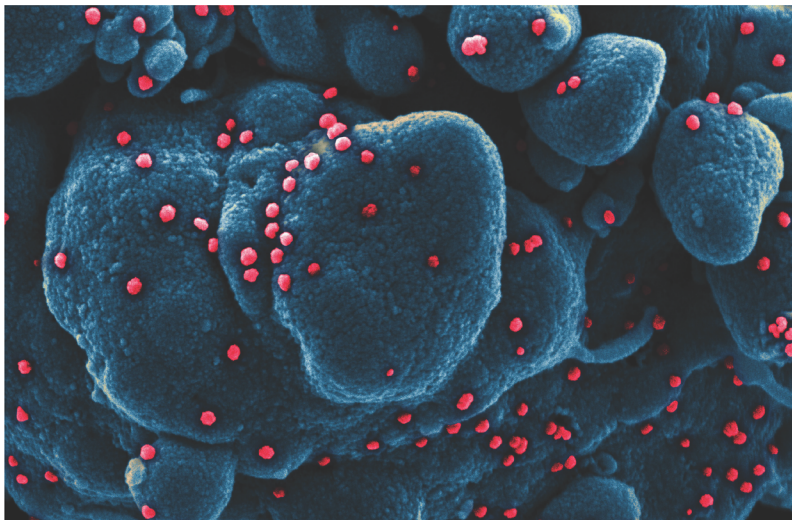
available on the  
Resilient Drug Supply Project website at:  
<https://www.cidrap.umn.edu/rds>

or directly at:  
<https://www.cidrap.umn.edu/sites/default/files/public/downloads/cidrap-covid19-viewpoint-part6.pdf>



# COVID-19:

The CIDRAP Viewpoint



## COVID-19: The CIDRAP Viewpoint

October 21, 2020

### Part 6: Ensuring a Resilient US Prescription Drug Supply

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CIDRAP, founded in 2001, is a global leader in addressing public health preparedness and emerging infectious disease response. Part of the Office of the Vice President for Research (OVPR) at the University of Minnesota, CIDRAP works to prevent illness and death from targeted infectious disease threats through research and the translation of scientific information into real-world, practical applications, policies, and solutions. For more information, visit: [www.cidrap.umn.edu](http://www.cidrap.umn.edu).

The PRIME Institute, founded in 1991 at the UMN, is an independent and global research, education, and consulting organization whose mission includes the study of economic and policy issues on pharmaceuticals.

The Walton Family Foundation is, at its core, a family-led foundation. It supports the work of the RDSP. To learn more, visit: [www.waltonfamilyfoundation.org](http://www.waltonfamilyfoundation.org).

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## Part 6: Ensuring a Resilient US Prescription Drug Supply

### Preface

Welcome to “COVID-19: The CIDRAP Viewpoint,” our series of reports that add key information, address issues that haven’t garnered the attention they deserve, and reflect the unique expertise among the CIDRAP team and our expert consultants. In our reports we address timely issues with straight talk and clarity. The steps we recommend are based on our current reality and the best available data. Our goal is to help planners envision some of the situations that might present themselves later this year or next year so that they can take key steps now, while there’s still time.

Our [first report](#) laid out potential pandemic scenarios, our [second report](#) covered crisis communication, our [third report](#) described “smart testing,” our [fourth report](#) was on contact tracing, and our [fifth report](#) covered surveillance.

Our hope is that these efforts can help you plan more effectively and understand the many aspects of this pandemic more clearly—and for you and your family, friends, and colleagues to be safer. Thank you.

– *Michael T. Osterholm, PhD, MPH, CIDRAP Director*

### Introduction

An ongoing crisis plagues US healthcare, limits reliable access to critical drugs, and results in serious consequences for patients who need these drugs. Over the past few years, the United States has had more than 250 drug shortages at any point,<sup>1</sup> many for critical medications, including both acute drugs for treating emergency situations and chronic drugs for managing serious long-term conditions. And shortages remain a perennial problem. Even though drug shortages have been recognized and tracked in the United States since 2001, the situation has not significantly improved in more than two decades.<sup>2</sup>

### Impact of COVID-19 on the Drug Supply Chain

Emergence of the COVID-19 pandemic in early 2020 has severely stressed the US drug supply chain. COVID-19 has jolted the global pharmaceutical market at all levels and production points. The supply side has been disrupted by production factory closures, shipping delays or shutdowns, and trade limitations or export bans. The demand side has seen dramatically increased need for COVID-19 therapies worldwide.

Shortages have limited critical drugs for treating COVID-19 patients, including propofol, albuterol, midazolam, hydroxychloroquine, cisatracurium, rocuronium, fentanyl, azithromycin, vancomycin, and others. In fact, 72.5% of them (29 of 40) currently have shortage problems, according to the American Society of Health-System Pharmacists (ASHP).<sup>3</sup> The US Food and Drug Administration (FDA), with more stringent criteria for declaring a shortage, currently shows 45% (18 of 40) on its Drug Shortage list. Both these rates (see the [Appendix](#)) are unacceptable.<sup>4</sup>

The pandemic has exposed many of the vulnerabilities in the US drug supply chain. COVID-19 tends to strike hard in a discrete geographic area, and when it creates a new hot spot, the hospitals in that area usually see a dramatic spike in admissions and ventilator use. In addition, use of certain critical COVID-19 drugs, such as azithromycin, may more than double overnight, while other drugs may see even steeper jumps of 5-fold (i.e., midazolam), 10-fold (cisatracurium), 20-fold (hydroxychloroquine) or even 40-fold (tocilizumab). Such explosive growth in critical acute drug use was seen in March and April when the number of hospitalizations and critical care COVID-19 patients in New York and New Jersey skyrocketed.

Many COVID-19 events have severely disrupted the global pharmaceutical supply chain. We saw stay-at-home orders and factory lockdowns in China,<sup>5</sup> followed by shipping port slowdowns and shutdowns.<sup>6</sup> Hubei province (and Wuhan city) in China alone had 37 pharmaceutical factories that held Drug Master Files for making active pharmaceutical ingredients (APIs) for US drug products.<sup>7,8</sup> Drugs made in the Hubei region include ibuprofen, hydromorphone, metoprolol, metformin, zidovudine, azithromycin, clindamycin, and levofloxacin.

Meanwhile, many Indian drug makers who rely heavily (about 70%) on China for key starting materials like benzene, as well as APIs, experienced delays in receiving the ingredients to make finished generic drug products for the global market.<sup>9</sup> In early March 2020, the Indian government was so concerned about having enough critical drugs to meet the needs of the Indian market that it restricted the export of 26 APIs and finished drug products to prevent shortages in India.<sup>10</sup> The drugs on India's export ban list accounted for about 10% of India's total pharmaceutical exports and included acetaminophen, metronidazole, erythromycin, clindamycin, and several essential vitamins.<sup>11</sup> India later prohibited the export of hydroxychloroquine because domestic stocks were running low and it wanted to first fulfill its own requirements.<sup>12</sup>

Other countries imposed trade limitations or export bans on pharmaceuticals, including the United Kingdom, which issued a ban on parallel export of 82 drugs, including insulin, amoxicillin, and acetaminophen.<sup>13</sup> China hinted in March that it might impose export controls on shipments of life-saving drugs to the US market, though it did not take that step.<sup>14</sup> This threat is particularly concerning

### *Pressing Issues*

1. US drug shortages pose a perennial problem; though drug shortages have been recognized and tracked in the country since 2001, the situation has not improved since then.
2. Drug shortages can be a matter of life and death, and some shortages mean that a life-saving drug is not available to US patients at any price.
3. Lack of visibility into the upstream drug supply chain severely hampers the ability of the market and of policymakers to monitor and address drug quality issues and facilitates market conditions that lead to drug shortages.
4. A number of serious threats to the US drug supply chain could precipitate a major shortage, intentionally or through natural causes, and such disruptions could lead to major healthcare consequences and costs.
5. The upstream US drug supply chain depends heavily on foreign sources for prescription drug products at all stages. The Food and Drug Administration (FDA) said in 2019 that officials do not know whether Chinese facilities are actually producing active pharmaceutical ingredients (APIs), how much they are producing, or where their APIs are distributed worldwide, and the agency lacks information to assess the effect on US manufacturing should China withdraw from supplying the US market.
6. Americans do not know where a given drug product was made or where it has been.
7. Information on US drug supply chain vulnerabilities is not transparent enough to support timely management of drug shortages and makes prediction of shortages nearly impossible.
8. While the FDA may have some of this information on a drug-by-drug basis, the drug sponsors and marketers consider the identity of the factory—or even the country—where a given drug is made to be proprietary.

because of China's dominance in the antibiotic market. China makes "nearly all" supplies of penicillin G and about 80% of the world's supply of many antibiotics.<sup>15</sup>

Many European Union (EU) countries and the United States looked to Italy as an alternate source of antibiotics when their supplies from China and India were disrupted. Italy was the EU's largest producer of antibiotics in 2018, accounting for 34% of the total EU consumption.<sup>16</sup> Italy, however, was hit early and hard by COVID-19 cases,<sup>17,18</sup> and, by early March, it had stopped all commercial activity (including drug factories) except for retail pharmacies and super markets, disrupting this alternate source.<sup>19</sup> By mid-March, most major European countries, including Spain, France, Germany, Switzerland, England, the Netherlands, Norway, Denmark, and Ireland, were severely affected by the pandemic.<sup>20</sup> Keep in mind that, in 2018, 19 of the top 20 brand name drug products in the United States were made overseas, mostly in Europe.<sup>21</sup>

### US Drug Shortages Persist

Certainly, drug shortages existed long before the pandemic and will likely persist long afterward. The FDA defines a drug shortage as "a period of time when the demand or projected demand for the drug within the U.S. exceeds its supply."<sup>22</sup> The FDA's definition reflects an economic framework based on supply and demand. This perspective is useful but inadequate, since it focuses primarily on fixing the problems after the market has failed, and results in patients not having access to the right drug when they need it. The American Society for Health-System Pharmacists (ASHP) defines a drug shortage as "a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent."<sup>23</sup> This definition uses both a supply chain/labor point of view and a clinical outcome framework. Despite their limitations, each of these perspectives is important to understanding the impact of drug shortages, but they have not been sufficient to significantly reduce them.

Drug shortages arise for many reasons, such as raw materials shortages, manufacturing capacity, production quality concerns, recalls, and business decisions to discontinue a drug product. Root causes are often not immediately apparent. US officials track drug shortages "after the fact" based on a manufacturer or a hospital reporting lack of drug product in the market. While this process is helpful to providers caring for patients and the retrospective tracking of shortages is important to understanding how to mitigate their potential impact, it has not been sufficient to significantly reduce the number of drug shortages.

Drug shortages are not just an inconvenience; they can be a matter of life and death. Last year, for example, vincristine—a pediatric cancer drug—was in severe short supply. One oncologist explained that vincristine is the "single most widely used chemotherapeutic (agent) in childhood cancer."<sup>24</sup> This was not an affordability problem, since the average sales price of a vial of vincristine is less than \$10. Instead, the drug simply was not available at any price. One of only two US manufacturers of vincristine exited the market, and the second experienced production delays and quality problems.<sup>25</sup> The vincristine shortage exposed a failure in the drug quality assurance system and in the robustness of the pharmaceutical market and supply chain.

Heparin, a widely used anticoagulant, is another example. Contamination of the key starting material for making heparin occurred at multiple suppliers in China back in 2007. This undetected adulteration of heparin led to dozens of Americans suffering severe consequences, including death.<sup>26</sup> Concentrated production in China set the stage for substitution of cheaper ingredients, which led to poor quality product reaching the market. Recalls and serious patient harm resulted from poor visibility into, and oversight of, product quality in the upstream supply chain for this drug product.

Both vincristine and heparin are injectable drugs used mostly in hospitals. Injectable drugs as a category have accounted for 50% to 70% of all drug shortages over the past two decades,<sup>1</sup> which is substantially larger than

### *Recommendations*

1. The United States should have a national process and infrastructure for analyzing, predicting, managing, and preventing shortages of critical medications.
2. An in-depth map of the US drug supply chain is needed to identify where each drug product in the US market was made, including where the starting materials, active pharmaceutical ingredients, and finished drug product were produced.
3. Congress should authorize and fund a national entity to build the map noted above, publish information on each drug's supply chain, acquire and analyze prescription drug expenditure data, estimate the consequences of failing to address drug shortages, and coordinate the development of related national policy.
4. This national entity could be an existing agency such as the Food and Drug Administration (FDA), National Institutes of Health (NIH), National Library of Medicine, or US Pharmacopeia Convention. Alternatively, a new federal entity may be established, such as the National Institute for Pharmaceutical Resilience (housed within NIH) or a Prescription Drug Policy Review Commission.
5. Prescription drug profiles for each drug product (at the National Drug Code level) should be made publicly available on a consumer-friendly website, with information as noted in the text (see page 10).
6. An ongoing research program on the resilience of the US drug supply chain should be conducted and include, but not be limited to, the development of a sentinel system that can detect signals that may precede a supply chain disruption or drug shortage.
7. The country should develop and regularly update lists of essential or critical drugs to be used for ensuring a high-quality and resilient drug supply for the military, triage during natural disasters, and the general public's need for critical drugs for both acute and chronic conditions.
8. Congress should authorize a federal agency (such as the FDA or Department of Health and Human Services) to prepare a response plan for managing and mitigating drug shortages and other supply chain disruptions.
9. Congress should authorize and fund a federal agency to monitor the changing landscape of pharmaceutical manufacturing and the supply chain for prescription drugs (see page 9 for key functions).

the share that injectables represent in the overall market. Only a few drug manufacturers produce and market generic injectable drugs. On the one hand, large hospital group purchasing organizations (GPOs) force the generic injectable drug companies to compete on price in exchange for large-volume purchases from hospital systems. Over time, however, as prices continue to decline, fewer manufacturers can afford to make these generic injectables and remain profitable in the market. These price reductions tend to lead to a single generic in the market and a single point of failure in the drug supply chain.

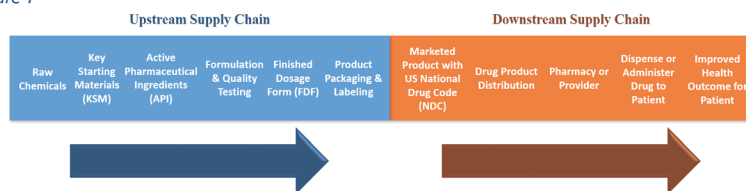
One way generic injectable manufacturers have managed to survive is to limit re-investment in modern production methods and in new production facilities, which also raises the risk of a drug shortage. At the same time, high economic and regulatory barriers to entry have limited new producers and competitors in this market.

There is no quick fix for either the quality issues or the economic market conditions that contribute to ongoing US drug shortages. Nevertheless, one obvious place to start is a detailed examination and understanding of the drug supply chain. There is an urgent need for new, more effective policy with robust transparency to solve the persistent drug shortage issues plaguing the US healthcare system for the active military as well as for the general population.

### Role of the Drug Supply Chain

Many steps in the drug supply chain are required to prepare a prescription drug product before it can be safely and effectively used by a patient. A simplified supply chain is shown in Figure 1. This supply chain includes not only points for production, refinement, processing, and packaging of a drug product, but each of the steps shown in the supply chain represent points at which the drug product, or its ingredients, may be transferred or shipped from one factory to another and sometimes from one country to another. The vast majority of the upstream supply chain for US drugs heavily depends on production and shipments in foreign countries, while the downstream supply chain from marketer to patient occurs almost entirely within the United States.

Figure 1



The pharmaceutical market has a complex, opaque structure. It is truly global, with various operations in the pharmaceutical supply chain from raw chemicals to finished dosage forms (FDF) (e.g., tablets and capsules) occurring in different countries. The more touch-points there are in a given drug's supply chain, the more potential points there are for supply chain disruption. Naturally, when there is only a single source of supply for a critical raw material or API, a single untoward event can disrupt the entire US or global supply of that product. The upstream supply chain for many drugs may face a serious threat of disruption, not just at one point but at multiple points. The supply chain works much like dominoes triggering a chain reaction.

Whether an upstream supply chain disruption occurs at a single point or multiple points, the effects are nonetheless felt downstream. Adjustments have to be made in the downstream distribution chain and ultimately in the healthcare delivery system.<sup>27</sup> Supply chain disruptions cause increased costs to drug marketers, wholesalers, health systems, pharmacists, and physicians. These disruptions create an open-ended healthcare cost liability for both public payers such as Medicare and Medicaid and private payers such as employer-based insurance and self-pay plans. Patients may suffer or even die if a needed drug is unavailable.<sup>28</sup> Overall, US health systems spend more than \$500 million a year on estimated costs related to drug shortages, with approximately \$200 million in direct costs and up to \$360 million on indirect costs.<sup>22,28,29</sup>

### Threats to the US Drug Supply

The US drug supply chain has been greatly stressed in recent years, even before the COVID-19 pandemic. We have seen, on average, more than 160 new drug shortages per year over the past decade.<sup>30</sup> Shortages often originate from issues in the upstream supply chain, such as materials availability, production capacity, or

product quality issues. In 2019, the country saw 186 new drug shortages, 82% of which were classified as due to “unknown” reasons largely because of the intentional opacity and secrecy of the upstream supply chain.<sup>1</sup>

Several major triggers may lead to a drug shortage, including: (1) increased demand (or medical need) for a drug, (2) unavailability of raw materials, (3) lack of production capacity, (4) poor quality processes and products, (5) disruption of shipping and transport, and (6) business decisions related to corporate priorities and profit. Some shortages have a single trigger, while others may have multiple triggers.

Shortages of critical need drugs may occur when a “trigger event” stimulates a crisis or disaster of some type at one or more places along the global supply chain. Trigger events that lead to drug shortages may be either a single point-in-time event (e.g., a hurricane) or an ongoing situation (e.g., COVID-19). These trigger events may occur because of conditions in the business, economic, climatic, political, regulatory, and technological environments.

The supply chain for a critical drug can be disrupted in many ways and have a serious impact on the US pharmaceutical market. The following scenarios are plausible, and in fact most have already occurred somewhere in the world. Potential threat scenarios include:

1. Climate change and natural disasters such as hurricanes, tornadoes, tsunamis, floods, infectious disease outbreaks and pandemics
2. Human behavior in response to actual or rumored drug shortages, including responses such as panic, hoarding, or changes in trust of therapies or vaccines
3. Human-made disasters such as fires, explosions, or nuclear disasters
4. Unintentional contamination while synthesizing and manufacturing a drug product (e.g., valsartan in 2018, ranitidine in 2019, and metformin in 2020 with nitrosamine contaminants)
5. Intentional contamination (or terrorism) of critical acute or chronic drugs during the synthesis, production, or distribution process
6. Business decisions and industry consolidation among drug firms
7. Bankruptcy or other economic behavior of a major pharmaceutical firm
8. Political or diplomatic crisis such as India’s ban on export of certain drugs this year
9. Military action or war with one or more major countries, such as China, North Korea, or Iran

The continued risk of drug shortages is not surprising, given the current structure and dynamics of the US pharmaceutical market. In 2019, two thirds of the US drug supply (by \$ value) is imported, while about 72% of the manufacturers of APIs that are used to make pharmaceuticals are located outside of the country.<sup>31</sup> Also, about 55% (based on \$ value) of biologics and specialty drugs are imported.<sup>32</sup> India is the major source of finished generics for the US market.<sup>33</sup> India depends on China for 70% or more of its API. And, for certain drug products, China accounts for nearly 100% of the API used for drugs such as penicillin G, levodopa, and acetaminophen and more than two thirds of the API for other major drugs including anti-diabetics, anti-hypertensives, anti-retrovirals, and other antibiotics.<sup>34</sup> Given the heavy reliance of the US drug supply on foreign sources, any of the above scenarios is plausible today, and many have to at least a certain extent already occurred.

If a threat scenario causes long-term consequences for the US drug supply, the fix is usually time-consuming. Most drugs have only a 1- to 6-month supply of product filling the entire supply chain. These limited levels of

inventory in the system are due, in part, to just-in-time production and pressures to minimize inventory-on-hand. In general, no alternative sources of drug supply exist to meet the needs of the entire US market since Americans consume about half of the world's drugs.<sup>35</sup> The efforts to get alternative production up and running to expand the supply of critical medications may take 3 months to 3 years or more.

If supply chain disruptions eliminate drugs for critical chronic conditions (e.g., diabetes, epilepsy, asthma), many patients without these "critical chronic" medications (such as insulin, phenytoin, or albuterol) would be hospitalized or die. Such disruptions could be even more widespread and more devastating than shortages for critical acute life-saving drugs.

### Need for Increased Supply Chain Transparency

A first step that would improve the US drug shortage problem would be a dramatic increase in transparency at every step of the supply chain. The current lack of transparency makes the timely management and resolution of drug shortages challenging and renders their prediction nearly impossible. Remarkably, a key FDA official reported to Congress in 2019 that FDA doesn't "know whether Chinese facilities are actually producing APIs, how much they are producing, or where the APIs they are producing are being distributed worldwide, including in the United States."<sup>35</sup> The FDA testimony went on to say, "Similarly, we do not have information that would enable us to assess the resilience of the U.S. manufacturing base, should it be tested by China's withdrawal from supplying the U.S. market."

While the FDA may have some of this supply chain information on a drug-by-drug basis, the drug sponsors and marketers argue that the identity of the factory, or even the country in which a given drug is made is "proprietary" and confidential. Often the US players in the downstream supply chain do not have meaningful visibility upstream past the US marketing sponsor. This limits the ability of policymakers and major purchasers to recognize vulnerabilities and to develop contingency and redundancy plans.

US consumers can find the "Country of Origin" on many products, such as foods, veterinary drugs, clothing, and electronics. "Country of Origin" is defined in US Customs and Border Protection regulations as "the country of manufacture, production, or growth of any article of foreign origin entering the United States."<sup>36</sup> This country-of-origin regulation, however, is not routinely followed for prescription drug products and is not enforced by US Customs inspectors.

The US Pharmacopeia Convention (USP) recently conducted a study of the labels for US prescription drug products,<sup>37</sup> based on drug labels available from the joint FDA and National Library of Medicine database known as DailyMed. USP analyzed the labels of 40,178 prescription drug products and found that only 3% reported the API manufacturer, 30% reported the finished product manufacturer, 45% reported only the labeler or packer, and 25% reported no information on the upstream supply chain. In other words, more than two thirds of prescription drug labels contain no information about who actually made the drug product and where it was made. As noted by the USP, "Manufacturers are required and do report suppliers to US FDA [but not to the public or on the labeling], also sharing supply chain information publicly could help providers proactively safeguard patient health. For example, when a safety issue is identified with an API manufacturer, providers will have on-hand information about impacted brands."<sup>38</sup>

If supply chain disruptions eliminate drugs for critical chronic conditions (e.g., diabetes, epilepsy, asthma), many patients without these "critical chronic" medications (such as insulin, phenytoin or albuterol) would be hospitalized or die.

In contrast to the US situation, information on the supply chain for prescription drug products in New Zealand is publicly disclosed and transparent. New Zealand collects and makes public the name and location of the API and the FDF manufacturers, in addition to the drug product sponsor and marketer in the country. The public transparency of this information does not appear to have commercially harmed the manufacturers or marketers of drug products in New Zealand. Many of the same corporate entities marketing drugs in New Zealand are marketing the same, or similar, drugs in the United States.

Data on the New Zealand Medsafe public access website<sup>99</sup> can be analyzed to quickly determine the sites of manufacture (API and FDF) of all critical drugs to determine which ones have the highest dependence upon a certain geographic location such as Wuhan, China, or Puerto Rico or any other location. Within hours of the news of a plant closure in China, New Zealand could know which drug products will be affected and can look for other producers of the same drug to supplement the country's drug supply.

If the United States adopted a similar transparency policy, both the FDA and public policy analysts could monitor the US upstream pharmaceutical supply chain to identify potential trigger points that could lead to supply chain vulnerability and to predict drug products that may face shortages in the United States. Potential points of vulnerability for drug products could be monitored and assessed for multiple factors. Drug purchasers could assess risk through a transparent database that identifies a drug product's supply chain in a manner similar to New Zealand's Medsafe. The drug product profile could also include information such as recall and seizure history of the drug product, FDA warning letters to the manufacturer, import holds, Form 483 citations of the manufacturing facility, and other quality control and regulatory actions.

### **Need for Resilient Drug Supply Database and Analysis**

The lack of information on upstream drug product supplies has resulted in serious health consequences for US patients and added substantial healthcare costs. Drug shortages can appear with little warning to healthcare providers (e.g., azithromycin, vincristine) and may require prescribers to look for alternatives, if any. At times, all or most of the suppliers of a given drug product (e.g., ranitidine) may face recalls at about the same time, leaving little or no drug product on the market due to inadequate production, inventories, or quality control measures. Business decisions can also deprive patients of critical drugs (e.g., vincristine).

The decades-long persistence of critical drug shortages demonstrates that a more systematic, comprehensive approach to ensuring a continuous, resilient supply of critical drugs is needed.

The country should have a national process and a common ongoing infrastructure for describing, analyzing, predicting, managing, and preventing shortages of critical medications to better inform policymakers and the public.

Building an in-depth map of the US drug supply chain will help identify where each drug product (at the National Drug Code [NDC] level) in the US market was made, including where the starting materials, APIs, and finished drug product were produced. The map should also track how the drug product is shipped from manufacturer to labeler (or marketer) to wholesaler and to the pharmacy or provider and consumer. This supply map should incorporate data from the FDA, suppliers and manufacturers, wholesalers, commercial sources, shipping records, and other sources. The map will be used to determine the networking and interdependence of suppliers at all levels in the supply chain and to report and assess its vulnerabilities.

Congress should authorize and fund a specific national entity to: (1) build an in-depth map of the US drug supply chain; (2) publish appropriate information on each drug's supply chain; (3) acquire and analyze data on the volume and expenditures for prescription drug products in the US market, including Medicaid, Medicare, other

government programs, managed care and commercial insurance, and cash pay markets; (4) estimate drugs with the most serious consequences of failure to mitigate or eliminate drug shortages; and (5) coordinate development of national policy related to the pharmaceutical market and ensuring a high-quality, resilient drug supply. This federal entity should design, develop, maintain, enhance, analyze, and publish information on the supply chain for all drug products (at the NDC level) in the US market. Market data should be combined with information on the supply chain patterns and related risk factors to prioritize drug products for which a shortage will have the greatest impact.

This national entity may be the FDA or another national agency such as the National Institutes of Health, the National Library of Medicine, or USP. Or a new agency could be established, such as a National Institute for Pharmaceutical Resilience (housed within NIH), or a Prescription Drug Policy Review Commission similar to the Medicare Payment Advisory Commission (MedPAC) could be created.

Prescription drug profiles for each drug product (at the NDC level) should be publicly available on a consumer-friendly website. The transparent information for each drug product should include:

(1) each major step in the supply chain, (2) manufacturer recall and FDA seizure history, (3) FDA warning letters, (4) facility inspections and Form 483 reports, (5) import holds, (6) marketing and advertising letters and warnings, (7) other regulatory actions, (8) public and private assessments of product quality using validated measures, (9) quality assurance reports, and (10) other relevant information.

An ongoing research program on the resilience of the US drug supply chain should include, but not be limited to, development of a sentinel system that can detect signals that may precede a supply chain disruption or drug shortage. This sentinel analysis system may use big data modeling and statistical techniques to look for potential and probable trigger events that are highly likely to lead to a drug supply shortage. Additional analysis should be performed to determine if the precipitating trigger events and predictive models for drug shortages are similar for all types of drugs or if different models and signals are needed for different types of drug products (e.g., critical acute drugs vs critical chronic drugs, injectable drugs vs oral solid dosage forms vs inhalers, or various therapeutic categories).

The United States should develop and regularly update lists of essential drugs to be used for ensuring a high-quality, resilient drug supply for (1) the active military, (2) triage during a natural disaster for a large population and for simultaneous disasters, (3) the critical acute drug needs of the general public, and (4) the critical chronic drug needs of the American public.

Critical Acute Drugs are those that, “when medically needed in acute care must be available and used within hours or days of the need or the patient will suffer serious outcomes which may include disability or death.” Also, the “absence of a Critical Acute Drug, or even the lack of availability of an effective substitute, may also lead to serious health outcomes or limited ability to provide humane care.” A list of 156 critical acute drug molecules has been identified by the University of Minnesota’s Resilient Drug Supply Project (RDSP).<sup>40</sup>

Critical Chronic Drugs are those that, “when medically needed must be available and used within a few days or weeks or the patient’s health will deteriorate, worsen substantially, or lead to serious outcomes such as

“An ongoing research program on the resilience of the US drug supply chain should include, but not be limited to, development of a sentinel system that can detect signals that may precede a supply chain disruption or drug shortage.”

hospitalization or death.” The vast majority of medical conditions are chronic diseases such as diabetes, high blood pressure, asthma, epilepsy, thyroid problems, and cancer. If a critical chronic medication is not available because of a drug shortage, some patients, such as type 1 diabetics without insulin, may experience serious problems.

The RDSP is developing a list of about 500 critical chronic drug molecules that should be among the first drugs to include on supply maps. The RDSP lists of critical acute and critical chronic drugs should be maintained and updated through collaboration with various stakeholders including the FDA, Department of Defense, National Security Agency, drug firms, wholesalers, retail pharmacies, hospitals, and others.

Congress should authorize and fund a federal entity (such as the FDA, Health Resources & Services Administration, Federal Emergency Management Agency, or Biomedical Advanced Research and Development Authority) to prepare a readiness and response plan for managing and mitigating drug shortages and other supply chain disruptions that arise in the US market. This plan should involve a nationally coordinated effort to tally remaining and limited supplies; establish rules, procedures, and priorities for allocating limited supplies; define the role of drug repositories; identify alternative supplies or alternative drug products; and establish other appropriate methods and responses for managing a drug shortage in order to provide critical drug therapy to patients in need.

Congress should authorize and fund a specific national entity to monitor the changing landscape of pharmaceutical manufacturing and the supply chain for prescription drugs, including steps to: (1) modernize drug production and quality; (2) monitor the safety, security and resilience of the drug supply chain; (3) track and trace the drug supply; (4) oversee trade policies and shipping security and safety; (5) require and enforce country-of-origin labeling for prescription drug products; and (6) implement supply chain transparency. This monitoring effort should lead to policy proposals to improve and ensure drug product quality and to incentivize increased drug manufacturing (both API and FDF) based in the United States in order to increase the quality, security, and resilience of the US drug supply.

Overall, the United States should have a national process and a common ongoing infrastructure for describing, analyzing, predicting, managing, and preventing shortages of critical medications to better inform policymakers and the public. This national effort should include certain public data elements on critical acute and critical chronic drugs that will be made transparent and will be provided through a public communication interface such as a website. The drug supply map and related databases will also include a confidential and comprehensive archival database for critical drugs with certain strategic information limited and accessible only to secure governmental and authorized industry stakeholders. This national effort will involve collaboration of multiple public stakeholders with select others to deploy strategic analytics and security tools to predict, prevent, and respond to future critical drug supply disruption, shortages, and related consequences.

### **Having Drugs Available When We Need Them**

In summary, prescription drugs are foundational to an effective healthcare system in the United States. Virtually everyone needs prescription drugs at some point, and they tremendously benefit both personal and public health. Americans count on drugs—particularly essential drugs for diseases, such as diabetes, chronic heart disease, and cancer—being available at the local hospital or at their community pharmacy. However, shortages are a serious and recurring problem resulting from a web of factors rooted in an opaque drug production and drug supply chain, underfunded and underperforming government agencies, and a drug purchasing and distribution system with product allocation practices that are often secretive, unknown, and counterproductive.

Drug shortages have only worsened in recent years, and drug product quality concerns are precipitating more widespread drug recalls. Continuing the status quo threatens our confidence in the quality of prescription drugs and their availability. Obviously, we need to shift from a “fail and fix” framework to a “predict and prevent” paradigm. Implementing the recommendations in this report will provide a new national entity focused on better understanding the complex reasons for drug shortages and will establish a systematic approach for analyzing, predicting, preventing, and mitigating drug shortages. With the support of policymakers and cooperation of the FDA and industry stakeholders, the US pharmaceutical market can significantly reduce drug shortages. Only then can we ensure a resilient supply of needed medications.

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**Appendix C**

**Resilient Drug Security & Supply Chain  
Project Objectives**

## Resilient Drug Security & Supply Chain

### Project Objectives

The Resilient Drug Security & Supply Chain project is being conducted to address the issues of drug shortages in the U.S. There are 8 major objectives of the project that will be addressed from October 1, 2018 to March 30, 2021.

**Objective 1: Critical Acute Drugs**

Identify a set of Critical Acute Drugs and the impact of drug shortages and supply chain disruptions and incorporate the efforts of the collaborative networks, findings, and action items identified in Year One.

**Objective 2: Essential Chronic Drugs**

Identify a set of Essential Chronic Drugs (i.e., drugs that would lead to patients perishing in a short period [days to months] if these drugs were not widely available in the U.S.) and the impact of drug shortages and supply chain disruptions for these Essential Chronic Drugs building on the work done being done on Critical Acute Drugs.

**Objective 3: Consequences of Drug Shortages**

Assess the relative importance of the Critical Acute Drugs and the Essential Chronic Drugs by a variety of factors such as: (a) number of people using them, (b) the severity of consequences due to absence of the drug, (c) the potential morbidity and mortality in the U.S. if a catastrophic event (i.e., health, social, economic, political, or other) happens, (d) the availability of reasonable therapeutic alternatives, and (e) other relevant and important factors.

**Objective 4: Mapping Drug Supply Chain**

Analyze and map the supply chain for each drug (i.e., Critical Access and Essential Chronic) from API to consumer using databases from FDA, commercial, shipping, and other sources and determine the dependence of each specific drug by country of origin. This task will build upon the databases examined in Year 1 (e.g., Panjiva, MediSpan, FDA) and will add other databases that provide new and unique information on the supply chain (e.g., IQVia, IBM Health MarketScan, New Zealand Medicines, RxResources, and others).

**Objective 5: Predicting Drug Shortages**

Use modeling techniques to identify the factors that may signal and precede supply chain disruption and drug shortages for Critical Acute Drugs and for Essential Chronic Drugs in the U.S. Determine if the models are similar across types of drugs (i.e., critical acute drugs vs essential chronic drugs) or type of trigger event precipitating a shortage or supply change issue.

**Objective 6: Prevention of Drug Shortages**

Identify methods and processes to prevent various types of events that could lead to widespread absence of Critical Acute Drugs or Essential Chronic Drugs. This task will include use of consultants from the stakeholder groups (i.e., FDA, DOD, NSA, brand and generic manufacturers, wholesalers, retail chains, hospitals and health systems, physicians, nurses, pharmacists, and consumers).

**Objective 7: Response to Drug Shortages**

Develop a response plan and approach for managing a supply chain disruption or a drug shortage for either a Critical Acute Drug or an Essential Chronic Drug including management of the existing and remaining or limited supply, distribution methods, use of repositories, allocation rules for medication use, and other appropriate responses.

**Objective 8: Market Change & Future Policy to Minimize Drug Shortages**

Describe the changing landscape of pharmaceutical manufacturing and the drug supply industry as a whole including steps to modernize drug production and the safety and security of the drug supply chain such as track and trace regulations, shipping regulations, and country of origin labeling. Policy initiatives derived from research and real world data on drug supply chains will be proposed and include policies to incentivize increased drug manufacturing (both API and finished dosage form) based in the U.S. in order to increase the security of the U.S. drug supply.

**Appendix D**

**Improving Resilience & Reducing  
Shortages in the Drug Supply Chain:  
Roles of the USP, CIDRAP & Others**

**Presented to:  
USP Council of the Convention  
May 12, 2021**

**Stephen W. Schondelmeyer, PharmD, MPubAdm, PhD, FAPhA  
Co-Principal Investigator, Resilient Drug Supply Project  
CMC Endowed Chair in Pharmaceutical Management & Economics  
Professor & Director, PRIME Institute  
Dept. of Pharmaceutical Care & Health Systems  
College of Pharmacy, University of Minnesota**

# Improving Resilience & Reducing Shortages in the Drug Supply Chain:

## Roles of the USP, CIDRAP & Others

*Presented to:*

### USP Council of the Convention

May 12, 2021

**Stephen W. Schondelmeyer, PharmD, MPubAdm, PhD, FAPhA**

Co-Principal Investigator, Resilient Drug Supply Project  
CMC Endowed Chair in Pharmaceutical Management & Economics

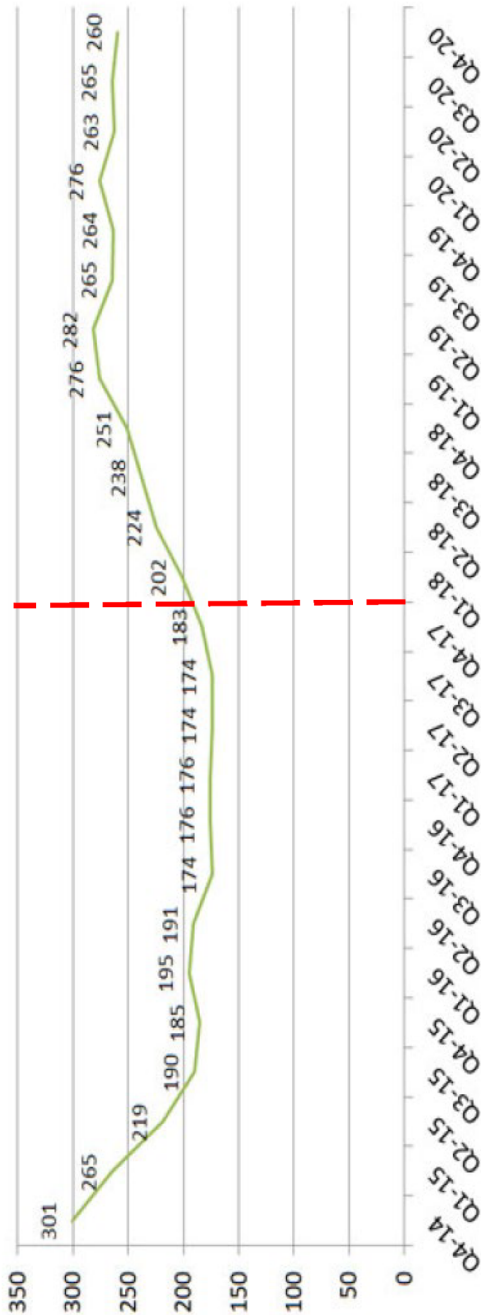
Professor & Director, *PRIME* Institute

Dept. of Pharmaceutical Care & Health Systems  
College of Pharmacy, University of Minnesota



# History of Drug Shortages in the U.S.

- **Drug Shortages Have Been Tracked in U.S. for More Than 25 Years**
  - > 200 Drugs in Shortage (per ASHP) Each Quarter from Q1-2018 to Q4-2020
  - Drug Shortages Have a Median **Duration > 1 Year**
  - Despite Tracking, Drug Shortages Have Not Significantly Decreased



<sup>1</sup> FDA. Drug Shortages: Root Causes and Potential Solutions. Report. Oct 2019

<sup>2</sup> Fox ER, Birt A, James KB, et al. ASHP guidelines on managing drug product shortages in hospitals and health systems. Am J Health Syst Pharm 2009 Aug 1;66(15):1399-406; and, ASHP website: <https://www.ashp.org/Drug-Shortages/Current-Shortages>.

# Definition of Drug Shortages in the U.S.

- Definition of Drug Shortage:
  - **FDA:**  
“A period of time when the demand or projected demand for the drug within the U.S. exceeds its supply.”<sup>1</sup>
  - **ASHP:**  
“A supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent.”<sup>2</sup>

<sup>1</sup> FDA. Drug Shortages: Root Causes and Potential Solutions. Report. Oct 2019

<sup>2</sup> Fox ER, Birt A, James KB, et al. ASHP guidelines on managing drug product shortages in hospitals and health systems.

Am J Health Syst Pharm 2009 Aug 1;66(15):1399-406; and, ASHP website: <https://www.ashp.org/Drug-Shortages/Current-Shortages>.

# Status of Drug Shortages in the U.S.

- FDA Drug Shortages <sup>1</sup>



- ASHP Drug Shortages <sup>2</sup>



<sup>1</sup> FDA. <file:///D:/IMYDocs/20D/!!!Drug%20Shortages%20&%20Foreign%20Dependency/Communications/CIDRAP%20Viewpoint/Viewpoint%20Oct%202020Website>  
<sup>2</sup> ASHP. <https://www.ashp.org/Drug-Shortages/Current-Shortages>

# Definition of Resilient Drug Supply in the U.S.

- **Definition of Resilient Drug Supply:**
  - **Resilient Drug Supply:**  
“A pharmaceutical market and drug supply chain that can recognize and respond to extraordinary increases in demand or disruptions in supply, or both, and still provide drugs that meet the needs of the American population.”
  - **U.S. Drug Supply:**  
“The U.S. drug supply focuses on providing optimal drug therapy to patients in the U.S. at the time that they need the drug, although the preparation, manufacturing, and finishing of those drugs is dependent upon an upstream supply chain that is truly global in scope and reach.”

<sup>1</sup> FDA. Drug Shortages: Root Causes and Potential Solutions. Report. Oct 2019

<sup>2</sup> Fox ER, Birt A, James KB, et al. ASHP guidelines on managing drug product shortages in hospitals and health systems. Am J Health Syst Pharm 2009 Aug 1;66(15):1399-406; and, ASHP website: <https://www.ashp.org/Drug-Shortages/Current-Shortages>.

# USP's Medicines Supply Map

- **USP's Medicine Supply Map Mission**
  - **Mission:** USP's Medicine Supply Map enhances transparency of the upstream pharmaceutical supply chain to help identify vulnerabilities and deliver insights that can guide risk mitigation strategies and investment in supply chain resilience.
- **Drug Supply Resilience Model**
  - **Goal:** identify, characterize and quantify risk and resilience in upstream supply chain
  - > 200 million data points & 20+ data sources (USP, FDA, CMS, EMA & private sources)
  - Visibility to identify vulnerabilities and lower quality risks
  - Leverage insights from ~22,000 locations where USP standards are used
  - Learn from USP's presence in global manufacturing hubs (India, China, Europe & U.S.)
  - Drug Supply Resilience Model is only one application of the Medicine Supply Map
- **Developed Pilot Project & List of Critical Drugs**
  - Pilot project developed jointly with *Angels for Change* & *Vizient, Inc.*
  - Identified Critical Pediatric Drugs (17 drugs)
  - Applied the Drug Supply Resilience Model to identify factors leading to shortages
- **Shortages of Critical Pediatric Drugs Are More Likely When There Is:**
  - More competition & prices are too low
  - Increased quality citations by FDA
  - Geographic concentration of production facilities

# CIDRAP's Resilient Drug Supply Project\* (RDSP)

- **Project Initiated in Fall 2018**  
**Mission:** The RDSP focuses on the global supply chain for each prescription drug used in the U.S. healthcare market in order to reduce or avoid disruptions from any cause and for any reason.
- **Develop Lists of Critical Drugs**
  - [Critical Acute Drugs](#) (156 drugs identified Dec. 2018)
  - [Critical COVID-19 Drugs](#) (40 drugs identified Jan. 2020)
  - [Critical Chronic Drugs](#) (~300-750 drugs (Brand, Generic & Specialty) products expected June 2021)
- **Map Supply Chain (pre-API to patient) for Each Drug in the U.S.**
  - Establish a drug supply, shortage, and tracking framework
  - Assess & characterize the root cause for each drug shortage (beyond FDA categories)
  - Conduct risk assessment along entire supply chain for drugs (up-stream & down-stream)
- **Predict & Prevent Drug Shortages**
  - Investigate effects of infrastructure failures (e.g., trade, transportation, power, geopolitics, economic)
  - Determine pre-cursors of shortages & methods to monitor & modify them
  - **Build a real-time, ongoing platform to assess & predict critical supply failures**

\* Funded by a generous grant from the Walton Family Foundation

# Defining Critical Acute Drugs

## Critical Acute Drugs:

"Drugs that when medically needed in acute care must be available and used within hours or days of the need or the patient will suffer serious outcomes which may include disability or death."

Absence of a **Critical Acute Drug**, or lack of availability of an effective substitute, may cause serious health outcomes or limited ability to provide humane care."

- **156** drug molecules
- **24.4%** (38/156) in shortage according to FDA <sup>(1-25-21)</sup>
- **38.5%** (60/156) in shortage according to ASHP <sup>(1-25-21)</sup>

# Defining Critical COVID-19 Drugs

## Critical COVID-19 Drugs:

---

"Drugs used in the active treatment of COVID-19 positive patients or their COVID-19 related symptoms."\*

\* This list was created by the Univ. of Minnesota's Resilient Drug Supply Project team in January of 2020.

Absence of a **Critical COVID-19 Drug**, or lack of availability of an effective substitute, may cause serious health outcomes or limited ability to provide humane care."

- **40** drug molecules
- **40.0%** (16/40) in shortage according to FDA (1-25-21)
- **70.0%** (28/40) in shortage according to ASHP (1-25-21)

Resilient Drug Supply Project:  
Critical Acute Drug List & Critical COVID-19 Drug List  
Drug Shortages Reported by ASHP & FDA

Drug #	Critical Acute Drug: Generic Name	Drug Category	UMN RDSP		ASHP		FDA	
			List of 150 Critical Acute Drug	List of 150 COVID-19 Drug	Drug Shortage List	Drug Shortage List	Drug Shortage List	Drug Shortage List
1	Clonazepam	Psychic	X	X	X	Yes	Yes	
2	Clonidine	Psychic	X	X	X	Yes	Yes	
3	Codeine	Psychic	X	X	X	Yes	Yes	
4	Succinylcholine	Psychic	X	X	X	Yes	Yes	
5	Ativan	Psychic	X	X	X	Yes	Yes	
6	Propofol	Sedation	X	X	X	Yes	Yes	
7	Morphine	Sedation	X	X	X	Yes	Yes	
8	Midazolam	Sedation	X	X	X	Yes	Yes	
9	Propofol	Sedation	X	X	X	Yes	Yes	
10	Phenobarbital	Sedation	X	X	X	Yes	Yes	
11	Remimazolam	Sedation	X	X	X	Yes	Yes	
12	Propofol	Sedation	X	X	X	Yes	Yes	
13	Etomidate	Sedation	X	X	X	Yes	Yes	
14	Propofol	Sedation	X	X	X	Yes	Yes	
15	Remimazolam	Sedation	X	X	X	Yes	Yes	
16	Hydroxyzine	Pain	X	X	X	Yes	Yes	
17	Morphine	Pain	X	X	X	Yes	Yes	
18	Oxycodone	Pain	X	X	X	Yes	Yes	
19	Hydrocodone	Pain	X	X	X	Yes	Yes	
20	Fentanyl	Pain & Fever	X	X	X	Yes	Yes	
21	Ativan	Pain	X	X	X	Yes	Yes	
22	Oxycodone	Medical Gas	X	X	X	Yes	Yes	
23	Stim. Oxide	Medical Gas	X	X	X	Yes	Yes	
24	Stim. Oxide	Medical Gas	X	X	X	Yes	Yes	
25	Stim. Oxide	Medical Gas	X	X	X	Yes	Yes	
26	Propofol	Respiratory	X	X	X	Yes	Yes	
27	Acetaminophen	Anti-infective	X	X	X	Yes	Yes	
28	Piperacillin-Tazobactam	Anti-infective	X	X	X	Yes	Yes	
29	Cefepime	Anti-infective	X	X	X	Yes	Yes	
30	Cefepime	Anti-infective	X	X	X	Yes	Yes	
31	Vancomycin	Anti-infective	X	X	X	Yes	Yes	
32	Droxychlor	Anti-infective	X	X	X	Yes	Yes	
33	Moxycycline	Anti-infective	X	X	X	Yes	Yes	
34	Clarithromycin	Anti-infective	X	X	X	Yes	Yes	
35	Clarithromycin	Anti-infective	X	X	X	Yes	Yes	
36	Linezolid	Anti-infective	X	X	X	Yes	Yes	
37	Amphotericin B	Anti-infective	X	X	X	Yes	Yes	
38	Amphotericin B	Anti-infective	X	X	X	Yes	Yes	
39	Amphotericin B	Anti-infective	X	X	X	Yes	Yes	
40	Cyproheptadine	Anti-infective	X	X	X	Yes	Yes	
41	Cladribine	Anti-infective	X	X	X	Yes	Yes	
42	Ganciclovir	Anti-infective	X	X	X	Yes	Yes	
43	Ganciclovir	Anti-infective	X	X	X	Yes	Yes	
44	Metronidazole	Anti-infective	X	X	X	Yes	Yes	
45	Amphotericin B	Anti-infective	X	X	X	Yes	Yes	
46	Netilmicin	Anti-infective	X	X	X	Yes	Yes	
47	Netilmicin	Anti-infective	X	X	X	Yes	Yes	
48	Pravastatin	Anti-infective	X	X	X	Yes	Yes	
49	Torsemamide	Anti-infective	X	X	X	Yes	Yes	
50	Amphotericin B	Anti-infective	X	X	X	Yes	Yes	
51	Posaconazole	Anti-fungal	X	X	X	Yes	Yes	

**WEEKLY UPDATE OF CRITICAL DRUG SHORTAGES:**

\* Critical Acute Drugs (156)

\* Critical COVID-19 Drugs (40)

**Shortages according to:**

\* ASHP Definitions

\* FDA Definitions

Note: This is a partial list. The complete and updated list is available at the RDSP web site: <https://www.cidrap.umn.edu/rds>

# Defining Critical Chronic Drugs

## Critical Chronic Drugs:

“Drugs that when medically needed in chronic care must be available and used within a few days or weeks of the need, and on a regular basis, or the patient will suffer serious outcomes which may include debilitating disease progression and worsening health status resulting in emergency care, hospitalization or death.”

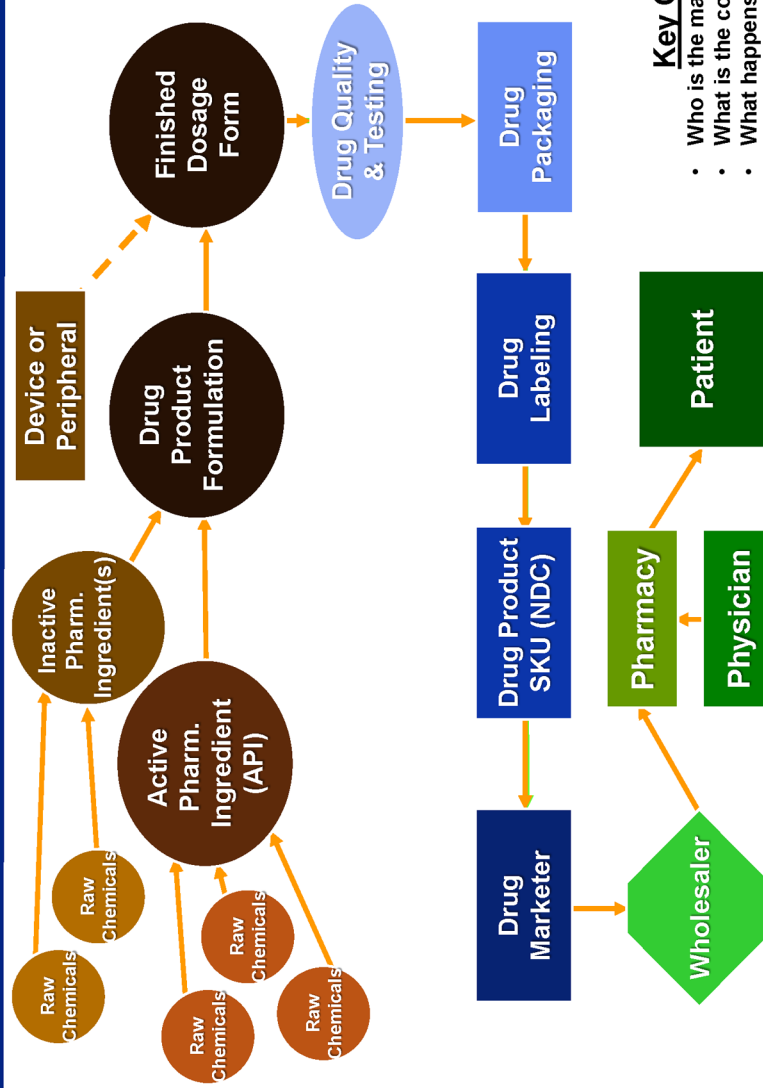
200

Absence of a **Critical Chronic Drug**, or lack of availability of an effective substitute, may cause serious health outcomes or shortened life span due to death.

The vast majority of medical conditions are chronic diseases such as diabetes, high blood pressure, asthma, epilepsy, thyroid problems, or cancer. For example, insulin is a Critical Chronic Drug for most Type I diabetic patients.

- **~500** drug molecules expected in list under development
- **? % ( ? /500)** in shortage according to FDA
- **? % ( ? /500)** in shortage according to ASHP

# Drug Supply Chain: Pre-API to Patient



**Key Questions:**

- Who is the manufacturer?
- What is the country of origin?
- What happens if API is not available?

# Contextual Factors Related to Shortages

1. **Natural Disasters, Weather & Climate Change** (e.g., hurricanes, tornadoes, tsunamis, floods)
2. **Health Disasters** (e.g., sanitation, infectious disease outbreaks, pandemics)
3. **Human Behavioral Responses** (e.g., stockpiling, hoarding, panic, or trust in science or vaccines)
4. **Human-made Disasters** (e.g., fires, explosions, nuclear disasters)
5. **Unintentional Contamination** while synthesizing & manufacturing a drug product  
(e.g., valsartan (2018), ranitidine (2019), metformin (2020) with nitrosamine contaminants; heparin with melamine)
6. **Intentional Contamination** (or terrorism) of drugs during synthesis, production, or distribution process  
(e.g., Tylenol poisoning, anthrax in the mail)
7. **Business Decisions & Industry Consolidation**  
(e.g., antitrust-Mylan API monopolization of lorazepam, vincristine discontinued by Pfizer)
8. **Economic & Ethical Behavior** of drug firms (e.g., bankruptcy of Purdue Pharma (opioids) & others)
9. **Political & Trade Relations** (e.g., India's ban on certain drug exports, UK-EU vaccine trade battle, China)
10. **Military Action or War** (e.g., hostilities exist with certain countries such as North Korea, Iran, Russia & China)

# Data Sources for Drug Supply Information

## Drug Products & Properties

- FDA NDC List & Medispan (NDC matrix with >750,000 active & inactive NDCs)
- FDA Approved Drugs & Biologics lists (> 15,000 current & former drug molecules)
- FDA List of Critical APIs & Other Critical Drug Lists (Acute, Chronic, COVID, drug shortages, pediatric, etc)
- Drug properties (e.g., molecular weight, stereoisomers, # of rings, years on market, ther. class, ref. std.)

## Drug Production & Supply Sources

- FDA Drug Registration & Listing System (~10,000 Drug facilities listed with FDA)
- FDA Drug Master File (DMF) list (~35,000 active & inactive DMFs for API)
- FDA NDC Structured Data Elements (NDSE) & Structured Product Labeling (SPL)
- NLM Daily Med website with Drug Product & Labeling lookup
- Other FDA data sets

## Drug Regulation & Quality

- FDA Drug Inspections (→ 483s, Official Action Indicated (OAI) citations, recalls, import actions)
- FDA Recalls & Seizures (Drugs with recalls or seizures)
- Regulatory Status (Patents, Exclusivities, orphan designations, generics & biosimilars)

## Market Demand & Economics

- Changes in Disease Incidence & Prevalence (e.g., # of other indications, new indications, seasonal)
- Sales of Drug Products (IQVIA data on price, revenue, # of Rxs, daily doses over time; U.S. & Global)
- Trade & Shipment data (imports & exports by country; shipments by land, sea, & air)

## Political & Business Environment

- Geographic & Economic concentration (API & FDF concentration, mergers & acquisitions, bankruptcies)
- Supply Chain Limitations (Foreign production, import-export climate, other)
- Trade climate (Sanctions, tariffs, incentives, political disputes)

## Other Information & Data

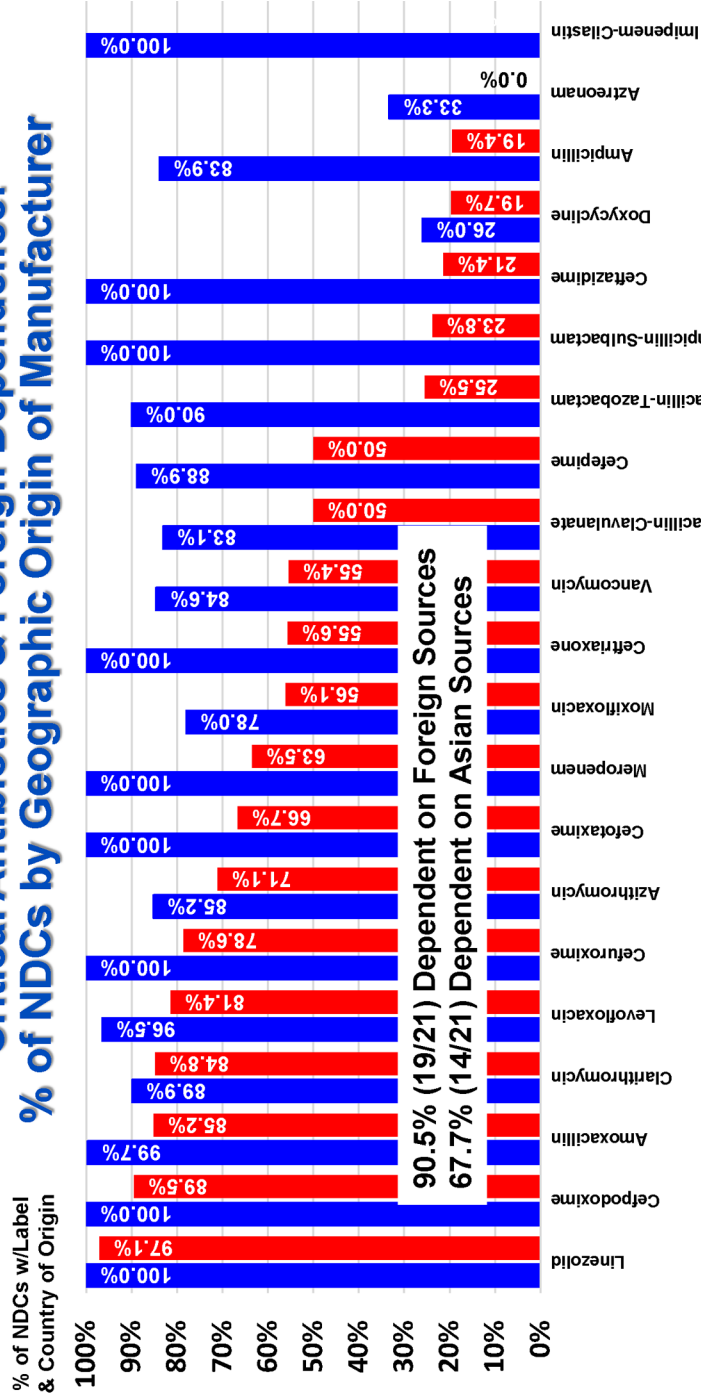
- Reference standard acquisition (USP), media mention of drug use, other

## U.S. Drug Supply's Foreign Dependence Based on Shipping Data for Critical Access Drugs: 2019

	China	Asia	Any Foreign
	<b>Critical Access Drugs with &gt;50% from China:</b>	<b>Critical Access Drugs with &gt;50% from Asia:</b>	<b>Critical Access Drugs with &gt;50% Foreign Source:</b>
	Hydrocortisone Doxycycline Acetaminophen Potassium Phenylephrine Fosphenytoin Epinephrine Sodium Phosphate Succinylcholine	Hydralazine Meropenem Dexamethasone Betamethasone Methylprednisolone Furosemide Torsemide Enoxaparin Heparin Mycophenolate	Azithromycin Lorazepam Midazolam Propofol Prednisone Warfarin Fentanyl Diphenhydramine Ampicillin Gentamicin Penicillin Insulin
<b>% of Drugs With Shortage in 2020</b>	<b>77.8%</b>	<b>80.0%</b>	<b>75.0%</b>

Source: Data is Average Annual % of Shipments to the US for Critical Drugs by Country of Origin from Panjiva (Shipments) Data for 2019.

## Critical Antibiotics & Foreign Dependence: % of NDCs by Geographic Origin of Manufacturer



■ Foreign Dependence (Production outside of the U.S.)  
■ Asian Dependence (Production in China, India, Taiwan, South Korea, Bangladesh and other Asian countries.)  
Source: Antibiotics Identified in Metlay J. et al. Diagnosis and Treatment of Adults with Community-acquired Pneumonia. Am J Respir Crit Care Med Vol 200, Iss 7, pp e45-e67, Oct 1, 2019. The Geographic origin of drug products at the NDC level were identified by extracting data from the FDA Drug Label Files as of February 2, 2020 and found at <https://dailymed.nlm.nih.gov/dailymed/spi-resources-all-drug-labels.cfm>.

# Drug Supply Map: Top 30 Generic Drugs

Rank	G001	G002	G003	G004	G005	G006	G007	G008	G009	G010	G011	G012	G013	G014	G015	G016	G017	G018	G019	G020	G021	G022	G023	G024	G025	G026	G027	G028	G029	G030
NDC#	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076	68882-0076
Product	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin	Aspirin
Drug Firm	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia	Pharmacia
Key Starting Materials	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
API Manufacture	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Finished Drug Manufacture	India	India	India	India	India	India	India	India	India	India	India	India	India	India	India	India	India	India	India	India	India	India	India	India	India	India	India	India	India	India
Pack & Label	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
FDA Sponsor (BA) (NDA /ANDA)	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA
Manufactured for:	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA	ANDA
Manufactured by:	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA
Distributed by:	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA
Wholesale & GPO Stock	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA
Pharmacy Stocks	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA
Patient	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA	USA

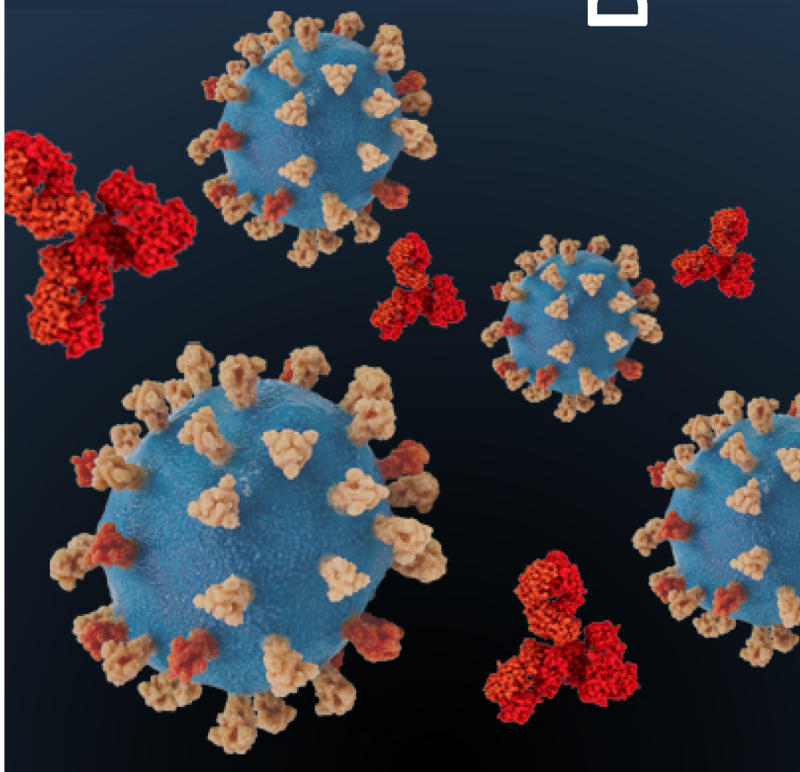
\* **90%** (27/30) of **API Manufacture** are **Unknown Sources**  
 \* **80%** (24/30) of **Finished Drug Manufacture** are **Foreign Sources**  
 \* **50%** (15/30) of **Packing & Labeling** are **Unknown Sources**

USA USA  
USA-Puerto Rico USA-Puerto Rico  
No-America (Mexico & Canada) No-America (Mexico & Canada)  
Europe Europe  
Asia Asia  
India India  
Not Reported Not Reported



**The U.S. Drug Supply**  
**(Both Brand & Generic)**  
**is Heavily Dependent**  
**Upon Foreign Sources**

# Impact of COVID-19 on Drug Shortages



# COVID-19 Exposed Long-Standing Vulnerabilities in the Drug Supply Chain

**The New York Times**  
**Essential Drug Supplies for Virus Patients Are Running Low**  
Medicines to alleviate breathing difficulty, relieve pain and sedate coronavirus patients are in very high demand, depleting stock around the country.

**The Washington Post**  
**Coronavirus raises fears of U.S. drug supply disruptions**  
Many pharmaceutical active ingredients are made in China

**FiercePharma**  
**Drugmakers struggle to meet demand for antidepressant Zoloft amid COVID-19**

**CBS NEWS** May 7, 2020, 8:39 AM  
**Pandemic exposes drug supply shortages doctors have grappled with for "more than two decades"**

**ONE BUSINESS**  
**The coronavirus exposed the US' reliance on India for generic drugs. But that supply chain is ultimately controlled by China**  
By Piyali Sin, CNN  
Updated 5:28 PM ET, Sat May 16, 2020

**tracelink**  
NETWORK FOR BETTER GOOD  
**COVID-19 is the Pharma Supply Chain's "Apollo 13" Moment**

# Impact of COVID-19 Pandemic on Drug Supply

## **Triple Play: Demand ↑, Supplies ↓ & Vulnerabilities Exposed**

### **Increased Demand**

- Global & U.S. Spread of COVID-19 Infection
- Increased Number of COVID-19 Cases, Hospital Admissions, Ventilator Use & ICU Care
- Non-Evidence-Based Claims of Effectiveness → Irrational Demand (e.g., Hydroxychloroquine)
- Fear of Shortages → Hoarding Behavior (e.g., Toilet Paper, PPE & Drug Shortages)

### **Disrupted Supply Chain**

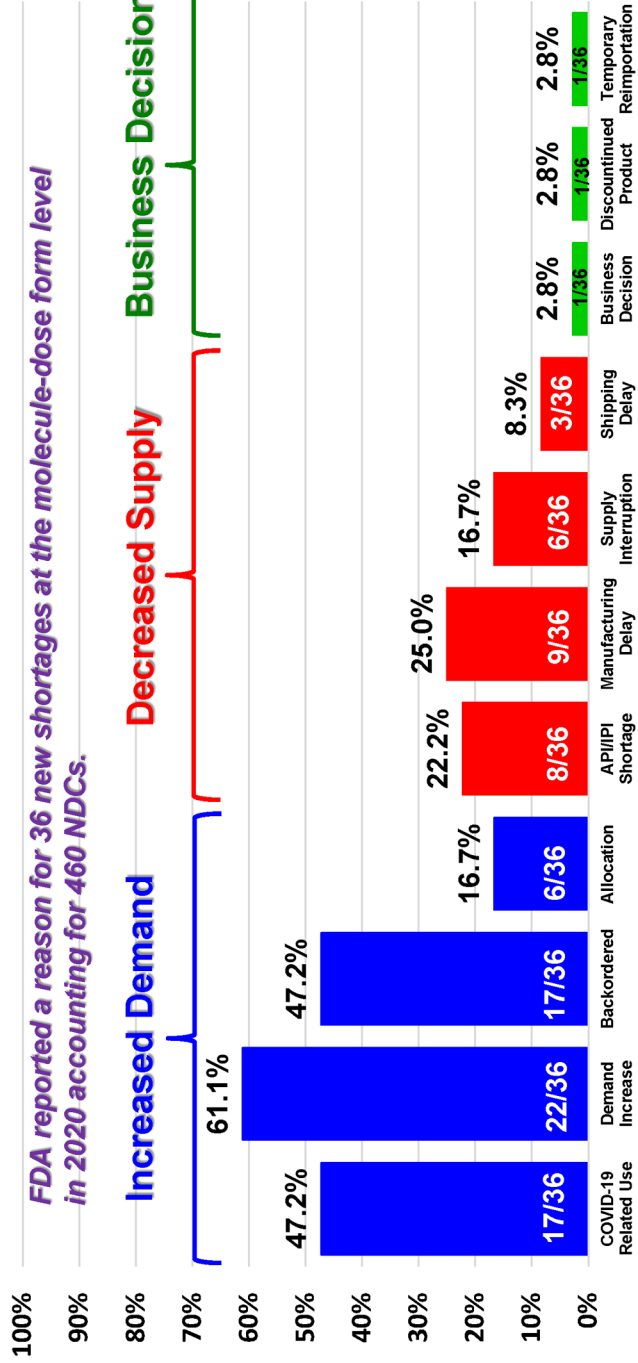
- Disrupted API Supplies: Factory Shut Downs, Port Closures & Other Shipping Disruptions
- Export Bans on API & Finished Drug Products
- Depleted Inventories at Manufacturers & Wholesalers
- Drug Product Allocation Limitations by Manufacturers & Wholesalers

### **Systemic Vulnerabilities Exposed**

- Manufacturers using “General Contractor” model rather than in-house manufacturing
- Aging & poor quality manufacturing facilities & processes
- Concentrated manufacturing including geographic, economic & sourcing issues
- Disparate regulatory environments & enforcement and limited inspection capacity
- Lack of transparency in the medicines supply chain

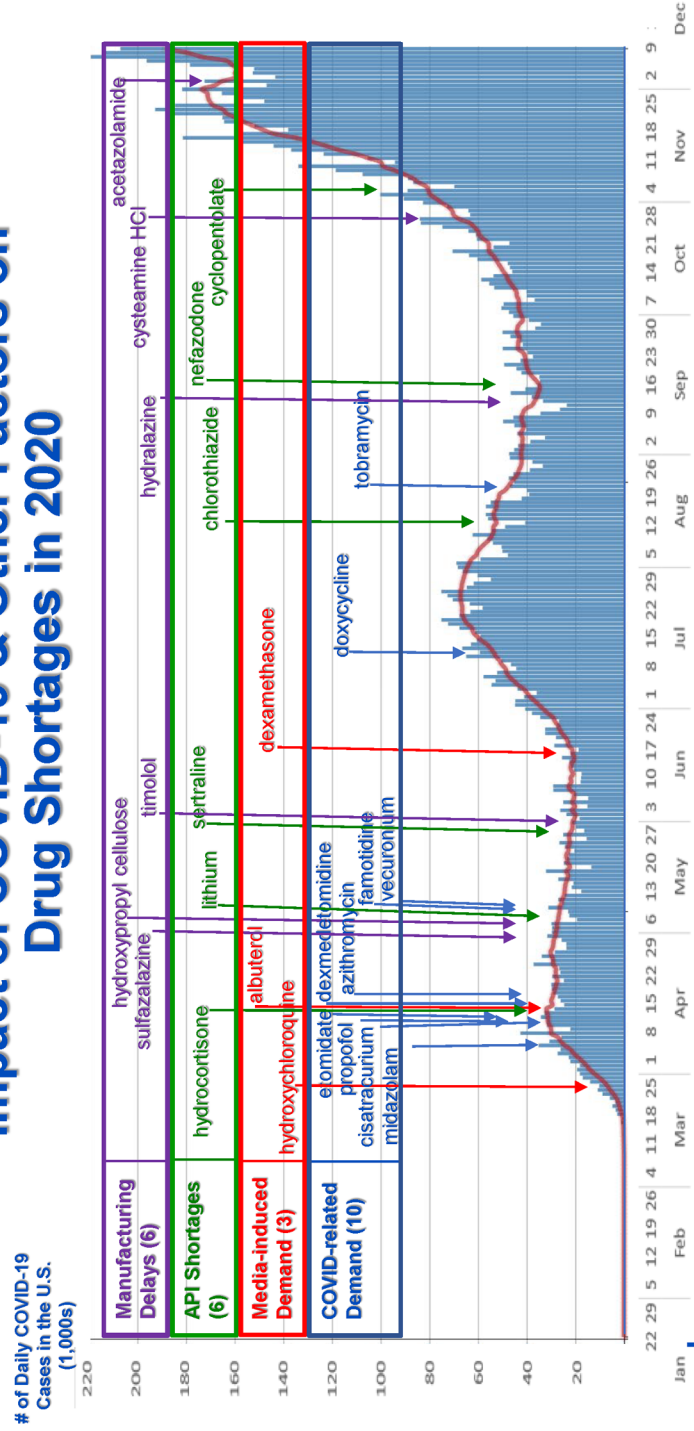
## Impact of COVID-19 & Other Factors on New FDA-Reported Drug Shortages in 2020

% of New Shortages With Condition\*



\* Shortages may have multiple factors so these percentages total to more than 100 percent.  
 Source: Based on data from FDA's Drug Shortage web site found on Dec. 5, 2020 at: <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>

# Impact of COVID-19 & Other Factors on Drug Shortages in 2020



Source: CDC COVID Data Tracker, Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, found on Dec. 5, 2020 at CDC web site: [https://covid.cdc.gov/covid-data-tracker/#trends\\_dailytrends](https://covid.cdc.gov/covid-data-tracker/#trends_dailytrends). Drug shortage data is based on data from FDA's Drug Shortage web site found on Dec. 5, 2020 at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfsr/shortages/default.cfm>. Based on preliminary analysis of factors related to each drug shortages.

## Recommendations for Ensuring a Resilient Drug Supply

- The U.S. should have a national process and infrastructure for analyzing, predicting, managing, and preventing shortages of critical medications.
- An in-depth map of the US drug supply chain is needed.
- Congress should authorize and fund a national entity to:
  - **Build the US Drug Supply Map**
  - **Make drug supply chains more transparent, and**
  - **Coordinate development of relevant national policy.**
- This national entity may be a new or an existing organization such as:
  - **US Pharmacopeia Convention** (an independent, scientific, non-profit organization)
  - National Institute for Pharmaceutical Resilience (*new entity at NIH*)
  - Prescription Drug Policy Review Commission (*new entity*)
  - Existing entity such as NIH, NLM or FDA
- Establish an ongoing research program on resilience of the US drug supply chain including, but not limited to:
  - Development of a sentinel system that can predict and prevent supply chain disruption
  - Reduction of the number of drug shortages and
  - Response to shortages if they do happen.

## **Beyond COVID-19:**

- \* Move Drug Shortages from:  
“A Fail & Fix Framework” to  
“A Predict & Prevent Paradigm”**
- \* Reduce & Eliminate Drug Shortages**

# Questions ? & Discussion . . . !

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Resilient Drug Supply Project  
**University of Minnesota**



PRIME Institute  
**University of Minnesota**



**Testimony of Kimberly Glas, President & CEO  
National Council of Textile Organizations**

**Senate Homeland Security and Governmental Affairs Committee Hearing on  
COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps**

**May 19, 2021**

Chairman Peters and Ranking Member Portman, thank you for the opportunity to testify on this subject that is so important to our nation, and to the U.S. textile industry and our workers.

My name is Kimberly Glas, and I am President and CEO of the National Council of Textile Organizations (NCTO), representing over 150 companies that comprise our membership. NCTO represents the full spectrum of the U.S. textile sector, from fiber through finished sewn products, as well as suppliers of machinery, chemicals, and other products and services with a stake in the prosperity of our industry. U.S. textile and apparel manufacturers produced \$64 billion in output in 2020, and our sector's supply chain employs more than 530,000 workers.

Textile manufacturing is considered an "essential" industry in the United States due to the many consumer, military, and industrial products that we manufacture, including personal protective equipment (PPE). In fact, the domestic textile industry supplies more than 8,000 different textile products for the U.S. military alone. The United States is also the world leader in textile research and development, with the U.S. textile complex developing next generation textile materials such as conductive fabric with anti-static properties, electronic textiles that can monitor heart rate and other vital signs, antimicrobial fibers, lifesaving body armor, and new fabrics that adapt to the climate to make the wearer warmer or cooler, and extruded fibers which incorporate semiconductors and microprocessors. Although often associated with labor intensive apparel manufacturing, the textile industry is actually one of the most capital and technology intensive of all modern manufacturing sectors.

In my remarks today, I will provide an overview of:

- The nature of the U.S. market prior to the pandemic and the root causes of America's dependence on offshore sources for medical PPE
- The heroic response of the U.S. textile industry to meet emergency PPE needs as the COVID-19 crisis intensified
- The federal government's response to COVID-19 and challenges that have complicated the ability of domestic textile PPE suppliers to expand output, and relevant solutions to address these challenges; and
- The need to adopt a series of precise policy and contracting recommendations designed to incentivize the establishment of a vibrant and permanent domestic PPE supply chain. The timeliness and urgency of these recommendations cannot be overstated as some companies

who stepped up to respond to this crisis are facing bankruptcy. These proposals include, but are not limited to:

- Create strong domestic procurement rules for federal PPE purchases and other essential products substantially similar to the Berry Amendment and the Kissell Amendment which require 100% US content from fiber production forward;
- Implement forward-looking policies to shore up the Strategic National Stockpile and issue long-term contracts to incentivize investment in the domestic PPE manufacturing base;
- Centralize contracting processes and standardize vetting procedures (purchasing fully made in America PPE);
- Create federal incentives for private sector hospitals and large provider networks to purchase domestically-produced PPE, the predominant critical purchaser of PPE in non-pandemic times;
- Continue to deploy the Defense Production Act to shore up the textile industrial base from raw materials to end products for all essential products. Provide other incentives to bolster this manufacturing industrial base -- a strong domestic textile industry will ensure the United States can respond in a crisis and beyond;
- Ensure we have strong trade policies and address dumping of imports and counterfeit/illegal products;
- Expedite and prioritize regulatory approvals for US PPE manufacturers to strengthen the depth and diversity of 100% US-made PPE offerings.

We particularly want to note the passage of the Portman-Peters Make PPE in America Act, that was reported out of committee last week. We cannot thank the committee enough for your unanimous support and we want to work closely with you to get this bill enacted into law quickly. This essential legislation as well as the other policies noted above will help ensure we have a strong healthcare industrial base long after the pandemic is over.

#### ***Catastrophic PPE Shortages: How Did We Get Here?***

U.S. textile manufacturers compete in one of the most unbalanced economic playing fields of any industrial manufacturing segment. NCTO has long called for a review of U.S. trade policy and the negative ramifications for the U.S. industrial base that stem from the aggressive, predatory practices of many of our foreign competitors and the lack of reciprocal market access for our products abroad.

The United States is the largest single-country importer of textile and apparel products overall as well as of PPE specifically. In 2019, the U.S. imported nearly \$125 billion of textiles and apparel—a record high—and ran a trade deficit of \$102 billion.<sup>1</sup> Furthermore, textiles and apparel ranks third, behind only electronics and transportation equipment, in terms of annual contribution to the U.S. trade deficit.<sup>2</sup> Notably, all of the top five contributors to the U.S. textile trade deficit are low-cost Asian producers, with China alone accounting for almost half of the deficit in our sector.

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<sup>1</sup> OTEXA Trade Balance Report

<sup>2</sup> U.S. International Trade Commission, U.S. Trade by Industry Sector and Selected Trading Partners for 2018, [https://www.usitc.gov/research\\_and\\_analysis/tradeshifts/2018/us\\_trade\\_by\\_industry.pdf](https://www.usitc.gov/research_and_analysis/tradeshifts/2018/us_trade_by_industry.pdf)

<b>Top 5 Contributors to U.S. Trade Deficit in Textile &amp; Apparel (Billion \$) (2019)</b>		
<b>Country</b>	<b>Trade Balance</b>	<b>% of Total</b>
China	-\$42.3	42%
Vietnam	-\$14.6	14%
India	-\$8.6	8%
Bangladesh	-\$6.2	6%
Indonesia	-\$4.7	5%
World	-\$102.0	

Source: U.S. Dept. of Commerce, Office of Textiles and Apparel,

Trade Balance Report

A confluence of major economic developments and various U.S. policy initiatives drove the massive expansion of foreign penetration into the U.S. textile and apparel market that began in the late 1990s and extended through the 2008 recession and beyond. Key U.S. policy decisions greatly exacerbated the contraction of U.S. textile and apparel manufacturing, including:

- January 1995 – WTO Multi-Fiber Arrangement Textile Quota phase-outs began
- December 2001 – China joins the WTO
- December 2001 – Vietnam is granted temporary normal trade relations status with the U.S.
- January 2005 – WTO Textile Quota phase-outs completed
- January 2007 – Congress approves Permanent Normal Trade Relations (PNTR) for Vietnam

The compounding damage associated with these policy factors to the U.S. textile industry in the 1997-2009 timeframe was severe. Over this period, U.S. textile and apparel production declined by 61 percent, employment decreased by a staggering 69 percent, exports fell by 15 percent, and the trade deficit in these products increased by 82 percent. This devastating downturn took place even as U.S. consumption of textile and apparel goods was expanding, with the U.S. population growing by nearly 12 percent and GDP up by almost 30 percent over the same time span.<sup>3</sup>

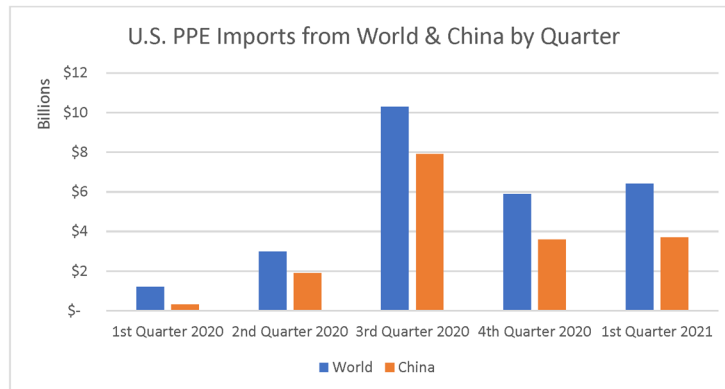
Following this period of precipitous declines, the industry has stabilized and in fact made a significant recovery in terms of overall output and exporting. However, the U.S. textile industry continues to be undermined by our competitors in the global textile and apparel supply chain, namely Asian countries that often grant limited access to their own markets, while employing a wide range of unfair trade practices, including, but not limited to: exploitative labor practices, government-subsidized production,

<sup>3</sup> <http://www.ncto.org/wp-content/uploads/2017/05/2017-05-10-Joint-Textile-Association-Trade-Deficit-Submission.pdf>

state-owned enterprises, currency manipulation, intellectual property theft, and lax or non-existent environmental standards.

The situation regarding PPE trade tracks along the same trends. According to a recent WTO report, the United States was the top importer of “personal protective products” in 2019 at over \$19 billion, followed by Germany at \$11 billion. The WTO report also demonstrated that the largest exporter of PPE by far was China at \$25 billion in 2019.<sup>4</sup>

According to PPE trade data now being tracked and reported by the Department of Commerce Office of Textiles & Apparel (OTEXA), U.S. imports of PPE grew from \$4.8 billion in 2019 to \$20.4 billion in 2020, an increase of 325 percent. Imports from China specifically jumped from \$1.6 to \$13.7 billion, up 756 percent to capture a two-thirds share of the U.S. PPE import market in 2020. The chart below further breaks down U.S. PPE import data by quarter to demonstrate the dramatic uptick in imports from China and their market share.<sup>5</sup>



China’s PPE sector has clearly benefited from state planning and predatory trade practices. Their “Made in China 2025” industrial policies were designed to nationalize and corner market share for these products, and these sectors have been further bolstered by massive government subsidies. In addition, there is now clear evidence that China’s PPE sector is tied to slave labor atrocities associated with the oppression of Uyghur and other ethnic minority groups in the Xinjiang province.

***U.S. Textile Industry’s Response to COVID-19***

<sup>4</sup> World Trade Organization, Trade in Medical Goods in the Context of Tackling COVID-19, Accessed at [https://www.wto.org/english/news\\_e/news20\\_e/rese\\_03apr20\\_e.pdf](https://www.wto.org/english/news_e/news20_e/rese_03apr20_e.pdf)

<sup>5</sup> U.S. Commerce Department Office of Textiles & Apparel, Personal Protective Equipment (PPE) Report and U.S. International Trade Commission Data Web

Noting the focus of today's hearing, there is much to learn from studying and acknowledging the overwhelming challenges the U.S. industrial base confronted at the onset of the pandemic. Massive PPE shortages were a direct function of allowing PPE supply chains to move offshore. A lack of focused public policy to bolster this essential manufacturing in the U.S. directly jeopardized the health and safety of our healthcare workers when global supply chains broke down. China's sheer dominance in the marketplace for these essential items further exacerbated the crisis when they chose to place export controls on PPE and raw materials as global demand surged, leading to shocking headlines revealing nurses wearing garbage bags and reusing or foregoing N95 masks.

As the United States faced devastating PPE shortages last spring, our industry received pleas from the highest levels of government to nurses and doctors on the front lines, asking for immediate assistance. The U.S. textile industry was honored to step forward and answer America's call during this time of national emergency. U.S. textile manufacturers quickly mobilized to find innovative solutions to the crisis, proactively retooling production lines and retraining workers to provide U.S.-made PPE to front-line medical workers and were critical suppliers to the U.S. government, including FEMA, the Strategic National Stockpile (SNS), and the Defense Department's (DoD) procurement office, known as the Defense Logistics Agency (DLA). They put aside competitive differences to construct multi-company PPE supply chains virtually overnight. In doing so, our members were able to manufacture and supply over 1 billion urgently needed items including face masks, isolation gowns, testing swabs, and their textile components at a time when global supply failed to meet the needs this crisis required.

Despite all their PPE production efforts, many U.S. textile companies were confronted with idle capacity, rampant cancellation of orders, plant closures, and workers being furloughed at the height of the pandemic. Orders for the military also declined because of COVID restrictions.

While there was some improvement in the latter months of 2020 and moving into 2021, sales are still not back to pre-pandemic levels. For the full calendar year 2020, clothing sales were down \$70 billion, or 26 percent, compared to 2019.<sup>6</sup> This historic downturn in demand led to many U.S. textile manufacturers operating at barely 10 percent of existing capacity beginning in March 2020. The collapse in demand has been felt throughout the entirety of the supply chain.

These grim statistics lead to the conclusion that U.S. textile manufacturers have suffered as much as any single segment of the U.S. economy because of the COVID crisis. Noting that our ability to make PPE long term in the United States depends on the overall health of a strong domestic textile industry, we must use all the tools necessary to ensure this manufacturing sector and other key sectors survive and thrive long after this pandemic is over.

This challenge is exacerbated now that PPE orders in the public and private sectors have largely subsided. With China re-exerting its dominance in the marketplace and as vaccines continue to be deployed, many companies are sitting with idle equipment purchased during the pandemic while struggling with legitimate concerns over the long-term viability of producing PPE in the United States. Other companies are wondering what the future holds for production moving into next year and the years to come. **Despite all the efforts that have been taken to re-establish domestic PPE production since the start of the pandemic, unless a number of critical policy solutions are advanced now it is clear that China will cement and expand its global dominance in the marketplace for these products for decades to come.** Our industry has a strong

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<sup>6</sup> Ibid.

sense of urgency to work with Congress and the Administration about getting key timely policies enacted before we, as a nation, are left vulnerable again.

***Federal Government's Response to COVID-19***

I would like to address our industry's experience partnering with the federal government over the past 14 months to mobilize and expedite PPE production, navigate the federal procurement process, and attempt to preserve these critical, reconstituted supply chains here in the U.S. permanently. It is our hope that this feedback will help inform the committee's work on identifying and supporting the various industry supply chains that make up our public health industrial base and how to fill response gaps.

**Engagement Pre-Pandemic:** To begin, I can briefly address the extent of our interaction with the federal government on public health supply chain management prior to the pandemic. In short, there was not much engagement to speak of for these products. The U.S. textile industry is a major supplier to the U.S. military, providing all of the mission critical textile-based needs for our warfighters, including uniforms, combat gear, carbon fiber-based ballistic protection, and beyond. The U.S. has long recognized the adverse national security implications of foreign supply chains on our military readiness. A military buy-American statute known as the Berry Amendment requires 100% US content in procurement, from raw inputs forward, which ensures U.S. content producers remain viable at all levels of the supply chain, and we maintain the workforce capable of manufacturing these items.

By contrast, we are not aware of any similar efforts to prioritize the domestic public health industrial base prior to the pandemic through supply chain mapping, identification of essential products, regular engagement with vital industrial sectors, or creating domestic purchasing requirements and investment incentives for manufacturers of textile-based PPE and manufacturers of essential medical supplies. Prior to the pandemic, few domestic suppliers had contracts with the federal government for PPE production or understood the Defense Production Act (DPA) and how it could be utilized. We must continue to foster these dialogues with industry in a detailed fashion in order to bolster the industrial base for essential products. As this committee looks for a model to adopt for valuing and advancing domestic production of vital items, we recommend looking to the work the Defense Department undertakes in industrial preparedness and, if critical areas for raw materials and end products are identified, continue to expand the industrial base using DPA and other mechanisms. We also believe gaps that have been identified in our textile defense industrial base must be further bolstered with U.S. government assistance. A strong defense industrial base creates a strong PPE industrial base.

**Engagement During the Pandemic:** It is important to note that, in a pandemic unlike anything experienced before in our lifetimes, even a fine-tuned federal procurement process may have challenges as the U.S. government attempted to respond to crises on multiple fronts.

As China was rationing its exports for both PPE and the raw materials to make PPE, we saw American nurses wearing makeshift trash bags for protection, and the realization was taking hold that 30 years of globalization with the Chinese dominating the marketplace left us extremely vulnerable and reliant on foreign supply chains when we needed these products the most.

In early March 2020, we began receiving urgent requests from domestic manufacturers, the federal government, members of Congress, state and local officials, and healthcare providers from across the country who were all looking for ways to solve this country's severe PPE shortage. NCTO played a key

role as the voice of domestic textile manufacturers in these conversations. We worked tirelessly to facilitate the connections and conversations necessary to form integrated supply chains, and deliver high quality PPE and critical medical products to our frontline healthcare professionals and to the U.S. government. We also engaged extensively with multiple agencies across the federal government, including the COVID response team, serving as the key industry contact point throughout the crisis.

While it is hard to predict the magnitude and severity of any multi-faceted crisis, it was apparent that the United States lacked a comprehensive strategic plan and prioritization for this critical industrial base. This is a lesson learned and should continue to be addressed moving forward before the we face the next healthcare emergency. I will outline from some of the challenges our industry faced during this time and provide key recommendations on what the United States government can do to help ensure that gaps in the federal response are eliminated moving forward.

**Varying Federal Government Contracting Processes:** During the pandemic, there were multiple agencies making substantial PPE purchases with several fits and starts to the contracting process that created confusion and lost revenue across the industry. HHS, FEMA, and DoD all made significant purchases of PPE during this time and there were key changes at the agencies who were acquiring PPE for the SNS and the bid process. At the height of the emergency, there were many conflicting demand signals that the U.S. textile industry had to navigate to supply the U.S. government timely, quality PPE.

As an example, federal contracting responsibility for an early solicitation from FEMA on behalf of HHS for the SNS was transferred to DoD, which created confusion on the part of U.S. manufacturers actively bidding on government PPE contracts. Manufacturers were initially told that DoD would order off of existing FEMA contracts, only to be informed later that this would not be possible due to conflicting procurement processes. As a result, companies had to file new bids for different agencies to supply the same product—even if they were already a supplier.

Although this move effectively reset the clock on the procurement process, the fact that the solicitations were then reissued by the Defense Logistics Agency was a welcome development based on our longstanding relationship with DLA and DoD's requirement to source military textile-based gear and other items domestically under the Berry Amendment. This provided a significant opportunity to get the full industrial base to work to supply essential PPE to the SNS to be deployed to frontline workers.

It was apparent to our industry early on that there was a lack of necessary coordination between HHS and DLA on specific procurement priorities and miscommunication between the agencies on the PPE required. By way of example, in May of last year, DLA issued a Request for Proposal (RFP) for reusable Level 1 isolation gowns. However, just days before projected awards were to be made, HHS determined Level 1 gowns were no longer needed and instead reconfigured the RFP to purchase an estimated 250 million Level 2-4 gowns, the vast majority of which would be disposable. Based on the volume and tight turnaround time associated with the original RFP, the U.S. textile industry ran millions of yards of fabric in advance to meet Level 1 reusable specifications which is consistent with industry practice in federal contracting. Pulling down the original RFP for Level 1 reusable gowns sent a confusing demand signal and led the industry to produce millions of yards of fabric with no destination.

You can imagine the severe frustration among U.S. companies that undertook significant expense to respond to the original RFP in an effort to supply lifesaving products amid the ongoing crisis. Several of these companies were forced to idle capacity and lay off workers, while excess inventory tied up

working capital. Further, we are also concerned with the pivot from reusable to disposable gowns, when reusable gowns represent a more sustainable and cost-effective option to the government and end users over time. When awards were made, NCTO and other industry organizations immediately raised concerns on the vetting process associated with certain awardees, including some newly incorporated companies with little track record and lack of financial credit winning multi-million dollar awards. Further questions were raised about whether items met the necessary health and safety standards which led DLA to do further post award vetting.

We do want to note that under a March 2021 RFP for reusable masks, we are very grateful to DLA for doing extensive pre-vetting and post-vetting of awardees and verifying the entire Berry-compliant supply chain before awards were made to ensure that companies selected met high product quality and manufacturing standards. Further, the detailed requirements and performance standards for the masks demonstrates the coordination between the agencies on this priority purchase. We believe it is important to highlight the value of awarding contracts to companies with a proven track record and ability to perform who can supply the U.S. government with quality PPE. We encourage the federal government to continue these practices on procurement moving ahead.

**Lack of Long-term Federal Contracts:** Virtually all federal PPE contracts during the pandemic have been restricted to short-term durations, averaging just 90-120 days. The Canadian government, by contrast, issued 10-year contracts to 2 separate N95 mask producers to foster investments in needed domestic capacity. The short-term approach here in the U.S. has had a chilling effect on U.S. investment as domestic textile manufacturers are reluctant to shoulder additional risks while simultaneously struggling with a historic downturn in traditional business resulting from COVID-19. Our industry wants to make significant investments in advanced manufacturing, like automated equipment to produce PPE, but manufacturers need longer-term, 3-to-5-year contracts to justify that investment. Providing a credible quantification of future PPE needs for the SNS through long-term contracting will help afford the assurances needed to incentivize investment in textile-based PPE manufacturing.

Recommendations for Key Contracting Reforms

The challenges posed by short-term emergency contracting as a standard practice can be mitigated by adopting several reforms that are designed to bolster private sector investment in U.S. PPE supply chains, including:

- **Issue Long-term Contracts:** The short-term PPE contracts issued in response to COVID-19 over the past 14 months do not provide the certainty that domestic industry needs to make the investments in our facilities and workforce to meet long-term PPE manufacturing goals. Our industry wants to make significant investments in automated equipment and advanced manufacturing to make PPE, but we need long-term contracts to help realize that investment. This contract certainty would provide added assurances and incentivize investment in equipment, hiring workers, and retooling operations.
- **Require Whole of Government Acquisition of Domestically Manufactured PPE:** The domestic supply chain for personal protective equipment is under enormous strain, leading to industry consolidation and company closures. To ensure the United States continues to have an innovative manufacturing base that can surge in times of urgency, it is imperative that Congress require DoD and adjacent agencies such as the Department of Homeland Security, the

Department of Veterans Affairs, HHS, and the Department of Justice (DOJ) to adopt policies similar to the Berry Amendment that require the domestic procurement of products essential to the health and welfare of our nation. Simply put, DoD is not a large enough and consistent enough customer for U.S. manufacturers and without the expansion of the addressable market for domestic products, the PPE industrial base will continue to decline.

- **Prioritize Best Value Government Contracting Over Lowest Price:** We encourage the federal government to utilize a multitude of factors when determining contract awards instead of price alone. This should take into account past performance and the viability of a potential awardee, examination of credit/financial capabilities, and the quality of the item procured to ensure it can meet healthcare standards. In addition, we would encourage the government to prioritize contract awards for manufacturers over distributors to help directly support production.
- **Verification of Potential Awardees:** We strongly encourage the U.S. government to implement thorough verification procedures for all awardees to understand capabilities, capacity, and ability to perform on contracts. For Berry-compliant products, we ask the U.S. government to verify the entirety of the supply chain to ensure the capacity is there to satisfy the requirements of any potential contract and that each item purchased meets high quality standards and share details on verifications/compliance standards and outcomes with industry.
- **Seamless Contracting Processes:** As the federal government is making further purchases of PPE, it is important to ensure a seamless contracting process if different agencies are doing purchasing for the SNS. As noted above when contracting moved from FEMA to DLA, there was confusion in this process. Further, since HHS is the lead purchaser of these items, it is imperative that a unified strategy is deployed to ensure that the requirements and needs are aligned across involved agencies and industry is given a consistent message.
- **Ensure DLA Leads Federal PPE Procurement Pending Enactment of Reforms:** Given that DLA values domestic manufacturing and procures these items under the Berry Amendment's strong domestic content and labor requirements, it is key for our emergent domestic PPE supply chains that DLA continues to be the federal government's PPE purchasing arm until Berry-like rules are instituted for other agencies. Currently, if HHS and other agencies make purchases, they are not required to purchase fully made in America PPE.
- **Prioritize Existing U.S. Partnerships Within the Western Hemisphere:** In addition to establishing a Berry Amendment rule for federal procurement of PPE, Congress should adopt a tiered contracting system that gives a secondary preference to producers in the Western Hemisphere. Specifically, after Berry sources are exhausted, priority should next be given to bids that utilize the joint production capacity of U.S. producers and our Western Hemisphere FTA and preference partners over Chinese and other foreign-made product. Doing so would help to stimulate PPE investment throughout the Western Hemisphere while simultaneously reducing our dependence on Asian supply lines that proved unreliable at the height of the pandemic.

These necessary contract reforms will help U.S. manufacturers better compete with offshore suppliers who often have significant price advantages due to government subsidies and in some abhorrent instances, forced labor.

**No Domestic Sourcing Requirements for Public Health PPE Items:** In addition to the challenges of short-term contracts, the lack of statutory mandates requiring domestic preferences for essential public health items has resulted in the rejection of numerous U.S. manufacturing bids to supply PPE. The absence of federal domestic purchasing requirements creates further uncertainty as to whether there will be a stable, long-term demand for U.S.-made PPE. Applying strong procurement rules will unequivocally lead to investments in this sector and help onshore the American PPE industry.

The recent disruption in global PPE supply orchestrated by China demonstrates that PPE self-sufficiency is a national security matter and justifies the need for domestic purchase mandates across all federal agencies for PPE and other critical medical supplies.

*Recommendations for Adopting Strong U.S. Procurement Rules for PPE*

To safeguard our public health security, we must establish strong, proven domestic procurement rules for federal purchases of textile-based PPE. While the President's Build Back Better initiative and recent Executive Order to identify ways to strengthen Buy American rules are a positive start, it is essential that Congress pass legislation that ensures our domestic supply chain is resilient and significantly stronger as we confront the next crisis.

The Berry Amendment, which governs textile-related defense procurement, should serve as a model for any new domestic procurement rules covering federal purchases of PPE. Our military leadership recognizes the importance of having a robust U.S. manufacturing base capable of servicing its mission critical needs. Otherwise, our national defense would be severely hampered in times of conflict by disrupted international supply chains and our military effectiveness beholden to the whims of potentially hostile regimes who control production through state-owned businesses. As with military procurement, new federal government domestic purchasing requirements for PPE will create the stable demand for U.S.-made PPE that will incentivize investment in and the viability of domestic PPE manufacturing by sending a strong and consistent demand signal from the federal government. When crafting domestic procurement rules, it is vital that exceptions to these requirements are narrowly tailored and any waivers should be issued only after thorough review of domestic supply chains, production capacity, and manufacturing gaps within industry. We are pleased to note that several DLA waivers issued early on during the pandemic for certain key items like gowns and N95s have been allowed to lapse in recognition of the significant domestic capacity that has come online throughout the pandemic. Further, our taxpayer dollars should not go to China and other foreign PPE producers, only to have those same offshore producers withhold access to vital supplies and equipment in the face of global shortages.

In this regard, we again commend the committee's support for S. 1306, the Portman-Peters Make PPE in America Act reported favorably and unanimously out of committee last week. In addition to the contracting reforms mentioned earlier, this bill also extends strong U.S. purchasing requirements for essential PPE to DHS and other federal agencies. We also note the important role that other pending legislation can play in expanding domestic production of essential items, and recommend the committee expedite consideration of these proposals as soon as feasible. Among these are The Homeland Procurement Reform Act (S. 1009/H.R. 2915) and the American PPE Supply Chain Integrity Act (H.R. 1466). Without the implementation of thoughtful policies such as those contained in these bills, what is left of the domestic PPE industry will continue to wither away and leave the United States exposed to future biological and viral threats.

**Incentivize Private Sector Purchases of U.S.-made PPE:** While federal purchases certainly support domestic production and U.S. manufacturing, the marketplace for American-made PPE should be as broad as possible to build and sustain our capacity. For instance, while the Berry Amendment is instrumental in supporting American textile manufacturing, defense orders on average account for only a fraction of our manufacturers' total production. Private sector demand drives domestic production. The private sector accounts for approximately 90 percent and above of purchases of these items in non-pandemic settings. This is an essential piece to onshoring this critical production chain long-term.

*Recommendations for Incentivizing Private Sector Purchase of U.S.-made PPE:*

Federal incentives should be created, such as tax credits and improved Medicare and Medicaid reimbursements for large private sector U.S. hospitals and provider networks purchases of American-made PPE. Doing so will help expand our domestic customer base for PPE beyond the federal government to the private sector, provide long-term stability to U.S. PPE producers, and enhance our national manufacturing capacity. Once this current pandemic subsides, U.S. private sector PPE demand has every motivation to chase the cheapest price for Chinese PPE. Without federal incentives for purchasing domestic PPE, our hospitals and communities will face the same PPE shortages when the next public health emergency arrives.

**Defense Production Act:** Since its inception, DPA has been utilized by the Defense Department to make critical investments in domestic manufacturing infrastructure and capacity. If deployed correctly, it can be a critical tool to help create immediate and long-term industrial capacity to manufacture essential medical PPE.

DPA has been an important tool for boosting certain essential items like N95 mask production. However, DPA appears to have been utilized relatively sparingly by the federal government in our specific sector. For example, while the U.S. government encouraged applicants to submit proposals for DPA funding during the pandemic, there was never a structured conversation with manufacturers to assess the government's overall needs. This led to confusion as to what resources would be available to build capacity for any gaps in the supply chain, along with uncertainty regarding the government's plan to address those gaps through deploying DPA to buy equipment, retrofit and modernize facilities, or meet other emergency capital needs. It is vital that industry understand the priorities for DPA funding regularly so that manufacturers can respond accordingly. Sometimes proposals are rejected with no understanding of the rationale for the rejection or redirection toward what the U.S. government may be seeking. Regular and clear communication with manufacturers is essential to help further align our shared interests and respond to the nation's priority needs. DPA is a critical tool that could strengthen the overall textile production base for PPE and other essential items – and we encourage the federal government to utilize it more robustly for our sector.

*Recommendations for Strategically Deploying the Defense Production Act*

We highly recommend better coordination with industry and a more expansive application of DPA funding to exponentially increase this program's effectiveness. The American textile industry welcomes the private-public partnerships that are created when the federal government makes capital investments under DPA. Further, incentives to invest in the manufacturing base coupled with DPA is also a critical tool to bolster domestic capabilities.

We also strongly recommend that DPA be used to diversify sourcing of critical products by creating redundant domestic supply chains. Pre-COVID, the United States had just one manufacturer of testing kit swabs located in Maine and one foreign manufacturer in Italy. DPA and federal funding has been utilized extensively to expand this essential production, but there has been no further federal funding to diversify swab production in the United States beyond this one producer. If something were to happen to that one producer, it would cripple our industrial health base for essential testing. Without diversifying production in the U.S. to help mitigate supply chain risk, we leave the United States vulnerable in a future pandemic. I represent an Ohio company that would like to expand their operations to be a critical surge/back-up producer and converted operations to making testing kits swabs—but their ability to stay in this market long-term will be hindered without federal investment. They have applied for DPA funding several months ago but to date have not received a response. This is the kind of project that should be an immediate priority for DPA funding. Diversifying federal investment in multiple production lines helps mitigate risk and strengthen U.S. resiliency.

Moreover, there are significant opportunities for the DPA to be utilized further to bolster both raw material inputs and finishing technologies to help ensure we are making globally competitive PPE products and other essential (military) items in the United States.

**Lack of Coordinated, Strategic Public Policy:** At present, our industry lacks a roadmap on long-term federal government contracts, has no U.S. domestic purchasing requirements for PPE with Berry-like contracting rules, is unaware of any long-term government strategy to invest in the U.S. textile industry, and there are no incentives for the private purchase of these products by hospitals and nursing homes. Without legislation to address these aspects, we remain severely vulnerable and dependent on Chinese dominated supply chains for decades to come.

A key aspect of this coordinated federal strategy should be comprehensive supply chain mapping and a capacity assessment of the U.S. public health industrial base.

*Recommendations for Adopting Coordinated Public Policy*

Congress and the administration can promote a comprehensive, unified federal government policy approach to domestic PPE supply chains through various steps, including:

- **Clear and Regular Communication with Industry:** It is essential moving forward that the administration and Congress have regular and clear communication with industry on the status of our industrial base, federal demand signals, and further policy tools that are necessary to foster onshoring critical manufacturing. These strategic dialogues play a crucial role in developing solutions to help expand this critical industrial base moving forward. This includes regularly mapping this critical supply chain to understand deficiencies and areas for investment.
- **Improvements for the Strategic National Stockpile:** Next, we need to improve and streamline the role that the SNS plays in preparing for and leading our national response to a national health crisis. The Stockpile must always be prepared to meet our public health needs efficiently and adequately during a pandemic or other public health emergencies. We must have well-stocked, current supplies on hand, sufficiently capable means for distributing these supplies, and the ability to quickly mobilize production to supplement supplies as needed. The U.S. should also develop a plan to cycle out products in the SNS and issue contracts to backfill these

critical products. These goals, plus comprehensive supply chain mapping, will require additional advance planning by the executive branch and proper oversight and funding by Congress.

#### ***Additional Recommendations***

As we exit the current crisis, rational federal policies are needed to ensure a stable overall environment where domestic supply chains for critical materials, such as PPE, can thrive in the United States. In that regard, NCTO has proactively coordinated with 20 additional trade associations and labor groups representing the entire domestic supply chain to develop and propose a commonsense approach to strengthening the integrated U.S. textile sector, including those engaged in PPE production.<sup>7</sup> We are united in our support for key policy and contracting improvements to address both our long-term goals of building, strengthening, and maintaining a U.S. PPE supply chain, and meeting the immediate PPE needs of our frontline health care workers, patients, and the general public. In addition to those already outlined above, we support additional improvements to U.S. public health policy including:

**Reassess and Address Imbalances in U.S. Trade Policy:** The above listed recommendations will only succeed under a broader policy framework that values U.S. manufacturing and its workforce. At a minimum, this broader framework must include the following:

- **Support PPE Tariffs:** Tariffs serve a critically important role in balancing the unfair advantages that non-market economies have over domestic producers. As we have discussed earlier, these advantages include government subsidies, state-owned enterprises, non-reciprocal trade policies, intellectual property theft, currency manipulation, and sub-standard labor and environmental policies. Congress needs to keep PPE tariffs on finished products in place to support U.S. businesses and workers and our FTA partners who abide by higher standards to earn duty-free access to our market. We also note that some tariffs for finished PPE products are at zero right now – which creates an unbalanced access to the U.S. market for some items and encourages the use of others. Congress must resist pressure to waive, delay, or reduce duties from massive importers who undermine U.S. manufacturing through an insistence on sourcing goods from countries that routinely employ these sub-standard practices.
- **Enforce U.S. Trade Laws:** The full force of our country’s investigative and enforcement capabilities must be unleashed to eradicate illegal and unfair trading practices. This would include steps to severely punish dumping and subsidy activities, and to block the importation of counterfeit goods and those made with slave labor and child labor. A top priority in this area should be the aggressive enforcement of the current Customs and Border Protection withhold release order on Chinese cotton and textile products made with forced labor. It is bad enough that China was able to deconstruct America’s PPE production chain through their extensive state planning and subsidies, it would be completely unacceptable to ignore the role that their reprehensible human rights abuses play in their dominance of global PPE markets. Furthermore, we must crack down on counterfeits. Regrettably, independent studies have

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<sup>7</sup> Joint Statement on Policy Objectives for Reshoring and Safeguarding Domestic PPE Manufacturing, <http://www.ncto.org/wp-content/uploads/2020/07/2020-07-20-Joint-Industry-Statement-on-PPE-Principles-Final.pdf>

verified that imported PPE often fails to meet basic health standards and puts our healthcare workers at risk. We must address these issues swiftly and aggressively.

***Conclusion***

The COVID-19 crisis has once again demonstrated the enormous contribution the U.S. textile industry makes to our overall economy and to our national and healthcare security. While we have suffered significantly due to market contractions and forced production shutdowns, we are confident that the domestic textile industry will exit the current crisis stronger and more agile than before the onset of the pandemic.

Further, the time is ripe for a revival of American PPE textile manufacturing. It has already begun, but we are at a pivotal point. Without the necessary policy response and support, our recent progress will be undone just as quickly, and China's stranglehold over global medical textile supply will be locked in for the foreseeable future with no reason to invest here. However, with the right policy framework, the domestic PPE supply chains built overnight can endure and grow, creating a level of self-sufficiency domestically that we have learned the hard way is essential to our national health and economic security.

Thank you for allowing me this opportunity to testify at this important hearing and to work on behalf of our members with this committee to enact rational policies to create a vibrant, permanent, and self-sufficient U.S. PPE manufacturing chain.



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**Statement  
of the  
American Hospital Association  
for the  
Committee on Homeland Security and Governmental Affairs  
of the  
U.S. Senate**

**“COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps”**

**May 19, 2021**

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to submit for the record our comments regarding the supply chain challenges faced by the hospital field during the COVID-19 pandemic, as well as our recommendations for strengthening the supply chain.

A strong and reliable medical supply chain is a critical and integral component to delivering safe and effective high quality care to patients; however, it has become increasingly clear that the level of fragility across our national medical supply chain is unsustainable and poses significant risk to hospitals and health systems, as well as the patients and communities they serve.

Hospitals rely on the effectiveness of the various groups that make up the supply chain, including manufacturers, sterilizers, distributors and, in many cases, group purchasing organizations (GPOs). A disruption anywhere in the process has the potential to create a series of prolonged difficulties in supply acquisition for providers, which ultimately can directly affect the patients they care for, the staff who provide the care or even the hospitals' ability to offer treatment at all. These disruptions can be the result of poor oversight, bad actors, policy initiatives and political motivations, as well as unforeseen and unpredictable events, like the COVID-19 pandemic or severe weather events.



Exacerbating these difficulties is the “lean” or “just-in-time” framework in which the medical supply chain currently operates, meaning there is effectively very little buffer when disruptions occur. Health care providers, distributors and manufacturers have pursued this just-in-time supply chain approach to lower costs so that health care is more affordable, but the pandemic has made clear the risks of such a strategy. When those disruptions occur, providers have little-to-no notice and can be left scrambling to acquire products necessary to perform the core functions of providing health care.

To mitigate these challenges, investment aimed at strengthening the supply chain is crucial. A focus on increasing manufacturing redundancy, diversifying where raw materials are produced and where products are manufactured, and growing capacity of the overall supply chain by “bulking up” and moving away from the “lean” approach will provide significant improvements (see figure 1 graphic). Hospitals and the communities they serve rely on adequate access to life-saving supplies and medications, and without substantial steps to strengthen the current framework, future health emergencies will result in the same shortfall our country recently experienced.

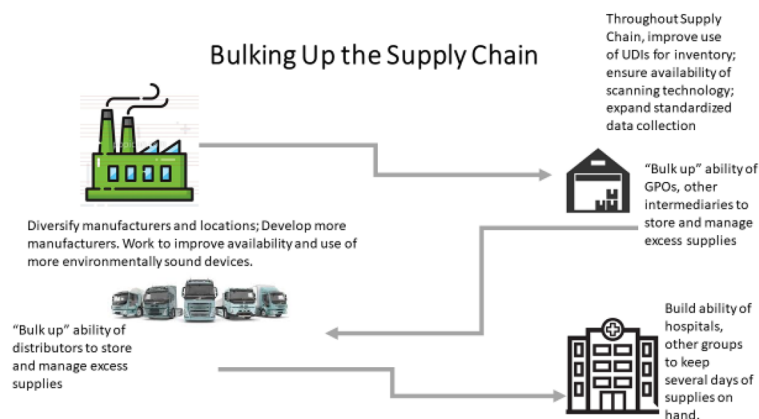


Figure 1: graphic depiction of changes needed to create a more resilient supply chain

#### **Recommendations to Strengthen the National Medical Supply Chain**

**The AHA urges Congress to take steps to strengthen the nation’s medical supply chain. America’s hospitals and health systems rely on the efficient and timely delivery of supplies so they in turn can deliver safe and effective care, especially in times of emergency. We support increased investments to maintain consistent and continuous access to medical supplies for hospitals and our entire health care system.**

- **Diversify manufacturing sites, as well as sources of critical raw materials, to ensure supply chain sustainability.** Currently, the U.S. relies heavily on both China and India for

the raw materials necessary to manufacture medical devices and pharmaceutical products. Further, many manufacturers of these products utilize manufacturing facilities located in China or India. The overwhelming reliance on a limited number of countries for the equipment and pharmaceutical products necessary to care for patients in the U.S. raises serious concerns and poses significant risks to patients and health care workers alike should a disruption occur. Congress and the Administration should encourage redundancy in the supply chain through policy initiatives focused on spurring diverse sites of production, including where possible, onshore manufacturing of critical active pharmaceutical ingredients and products.

- **Support advancements in reuse and reprocessing technologies to mitigate supply challenges while decreasing waste and environmental impact.** The COVID-19 pandemic required providers and manufacturers to adapt quickly to minimize the impact of supply shortages on patients. Several adaptations warrant additional consideration and investment to strengthen the supply chain for the future. For example, efforts to reuse or repurpose certain medical devices, like respirator masks, proved critical when supply was scarce. Continued investments in these technologies can help providers navigate future supply shortages while also decreasing the amount of waste associated with the production and discarding of traditional single-use devices.
- **Invest in new product development.** Opportunities exist to incentivize the development of new products that can be manufactured without raw materials sourced in the U.S., thus increasing the reliability and long-term sustainability of our domestic supplies. Additionally, investments in virtual inventory technology programs that function as supply “control towers” could ensure more accurate product visibility and aid in efforts to identify when supply capacity is approaching demand.
- **Develop and adapt certain data standards to aid in early detection and mitigation of supply shortages.** Disruptions to the supply chain can force hospitals and health systems to cancel non-emergent procedures or delay non-emergent care due to a lack of critical supplies meant to keep both health care workers and their patients safe. In those instances, increased adoption of certain data standards, like the Unique Device Identifier (UDI), and computerized supply systems can enhance inventory management, transparency and the early detection of supply shortages with the goal of resolving the issue before it significantly affects patient care. Further, investments in the purchase of product scanning technology at the point of use can allow providers to quickly assess utilization, recognize upcoming shortages and take steps to resolve them. Increased adoption of both the UDI and scanning technologies will improve multi-directional information sharing and data analytic capabilities across the health care supply chain.
- **Increase end-user inventories and incentivize additional cushion.** The current just-in-time approach to supply chain logistics functions is outdated. The COVID-19 pandemic highlights the real risks this process has posed to patient and health care worker safety, and the provision of vital hospital services. Steps need to be taken to “feed” the supply chain with the goal of ensuring enough product is available, or capable of being made available, when demand increases. For example, supporting an increase in end-user inventory of critical supplies and medications across the existing manufacturing and distribution infrastructure in the U.S. will help add necessary capacity to the existing supply chain.

Further, these actions will decrease the need for large national and state stockpiles, which can be difficult to manage and maintain and present significant operating cost, product expiration and waste issues. Finally, efforts to increase on-hand inventory for end-users allows manufacturers and distributors to increase production capacity, while also putting providers in a position to have enough access to supply in instances where demand spikes but additional measures like the Defense Production Act have not yet been invoked.

**Conclusion**

The health care supply chain faced unprecedented strain over the past year due to the high demand for personal protective equipment and other medical supplies, both domestically and abroad, during peak periods of the COVID-19 pandemic. Significant federal investment is needed to strengthen the national medical supply chain to ensure the country is prepared for future public health emergencies. We look forward to working with Congress to strengthen the nation's supply chain resiliency.



U.S. SENATE COMMITTEE ON HOMELAND SECURITY & GOVERNMENTAL AFFAIRS  
“COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response  
Gaps”

Written Statement of

**Ravi M. Anupindi, PhD**

Chair, President’s Advisory Committee on Labor Standards and Human Rights at the University  
of Michigan

Colonel William G. and Ann C. Svetlich Professor of Operations Research and Management

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Submitted May 24, 2021

Chairman Peters, Ranking Member Portman, and Members of the Committee on Homeland Security and Governmental Affairs.

My name is Ravi Anupindi. I currently serve as a chaired professor of operations research and management at the Ross School of Business, University of Michigan (Ann Arbor). My academic career has been dedicated to study of global supply chains; for over a decade now, I have also studied global healthcare supply chains. In the Summer-Fall of 2020, I co-lead a study, supported by the University of Michigan Institute of Health Policy and Innovation on the *Scale-Up of COVID-19 Testing in the State of Michigan*<sup>1</sup>. Most recently, I served as one of the two faculty experts on the *Global Supply Chain Task Force: Reimagining the Global Supply Chain Post Covid-19* (henceforth referred to as P2P-GSCTF) that just released its report<sup>2</sup>; the task force was convened by Principal to Principal and chaired by Congressman Joe Crowley and former Congressman Mike Rogers. I presently co-chair of the National Academies of Sciences, Engineering and Medicine (NASEM) *Committee on Addressing Issues of Vaccine Distribution and Supply Chains to Advance Pandemic and Seasonal Influenza Preparedness and Response*<sup>3</sup>; while the focus of this committee is global access to vaccines, some of the supply chain lessons are common. Finally, for more than a decade, I have worked with the private sector on global supply chain risk and resilience and currently serve on the governing council of an industry group called the *Supply Chain Risk Leadership Council (SCRLC)*<sup>4</sup>.

My comments in this statement are based on a synthesis of my experiences and learning from the above engagements. I thank the Committee for giving me an opportunity to share my thoughts on the critical role of supply chains in pandemic preparedness and response, the experience of U.S. during the current pandemic, and some suggestions future preparedness.

#### COVID-19 RESPONSE, MEDICAL SUPPLY CHAINS & GAPS

Needless to say that the COVID-19 pandemic has had a devastating effect on lives and economies across the world. More than 600,000 people lost their lives in the US and it is estimated that we would have suffered a GDP loss of nearly \$5 trillion. The pandemic exposed vulnerabilities in supply chains across many industry sectors (e.g., essential commodities, food, etc.) but critically felt with devastating impact in our end-to-end healthcare supply chains that includes both the upstream supply chains of health commodities as well as the downstream supply chains to health facilities and laboratories. We have seen severe shortages of Personal Protective Equipment

<sup>1</sup> *COVID-19 Testing Scale-Up: Key Issues and Considerations for Michigan Policymakers*, IHPI Brief, October 2020; <https://ihpi.umich.edu/news/u-m-researchers-examine-ways-scale-covid-19-testing-meet-demand>

<sup>2</sup> *Principal to Principal Global Supply Chain Task Force: Reimagining the Global Supply Chain Post Covid-19*, Final Report. May 2021. <http://principaltoprincipal.us/news-announcements/>

<sup>3</sup> <https://www.nationalacademies.org/our-work/addressing-issues-of-vaccine-distribution-and-supply-chains-to-advance-pandemic-and-seasonal-influenza-preparedness-and-response>

<sup>4</sup> <http://scrlc.com>; members of SCRLC are leaders in their respective sectors including companies like Boeing, Cisco, Johnson & Johnson, John Deere, and others.

(including N95 masks), test kits and supplies (reagents, swabs), ventilators, medicines, etc. impacting patients and the ability of frontline healthcare workers to deliver care.

In the early days of the pandemic, the country struggled to scale up COVID-19 testing handicapping us to control disease spread through early detection of cases and follow up actions including contact tracing and isolation. In the summer and fall of 2020, we conducted a detailed study of challenges to scale up COVID-19 testing interviewing more than 20 experts, including state leaders, public health experts, laboratory directors and epidemiologists and examined process, supply chain, and governance issues. Increasing demand for testing with unpredictability of access to testing supplies (reagents, swabs, etc.) made planning hard and led to significant increase in test turnaround times. Many labs were technologically ill equipped to share test results with the state impeding follow up actions of tracing and isolation. The supply logistics to labs was fragmented, overwhelming health workers who had to manage sourcing and logistics instead of focusing on clinical work. There was general lack of visibility into testing network capacity and supplies. Inconsistent data reporting across states hampered national response. Manufacturers of test kits and supplies received conflicting and splintered signals of demands from multiple entities, viz., labs, state governments, and the federal government, making it hard for them to accurately determine true capacity needs and take necessary actions to scale up. While the state and the federal government was focused on increasing testing capacity, needed investments were insufficient; firm commitments to increase capacity that businesses would have liked to see were less forthcoming and little attention was given to test turnaround times – a key metric. The following picture emerged from our study. Despite well-meaning actions by numerous individuals and agencies, gaps in governance and management of the network comprising of end-to-end supply chain and operations from labs downstream to manufacturers of test kits and supplies upstream and all the agencies in between, led to severe challenges in managing the spread of the virus. Slow scale-up of testing also impacted our ability to keep the economy functioning.

In our P2P GSCTF study, completed in collaboration with our partners that included US based domestic and global companies as well as international companies, we looked deeper into supply chains of pharmaceuticals, medical equipment, and PPE. Our study was informed by interviews with senior executives in related departments and agencies of the United States Government (USG), state and local officials, senior public and private hospital system administrators, other industry representatives, and additional policy experts. These discussions gave us a deep insight into the state of USG's preparedness and fragmented response to the pandemic impacted by vulnerabilities in global supply chains of critical medical goods to quickly scale up. The task force focused on identifying underlying issues and solutions through the lens of strengthening U.S. national and economic security; these are outlined in detail in the report<sup>5</sup>. Here I will briefly highlight my observations on some of our main findings and recommendations.

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<sup>5</sup> *Principal to Principal Global Supply Chain Task Force: Reimagining the Global Supply Chain Post Covid-19*, Final Report. May 2021. <http://principaltoprincipal.us/news-announcements/>

To better understand the current state of the nation on preparedness and response, I reviewed our National Response Frameworks. These are thoughtfully put together, comprehensive and very useful to deal with local / community level responses that are book-ended in time (e.g., dealing with floods, earthquakes, etc.). However, the frameworks are, in my opinion, inadequate to address a pandemic that is by nature national / global and sustained over much longer time periods as we have experienced. The pandemic playbooks that do exist, while comprehensive in identifying the various threats and outlining a decision framework & relevant agencies, are not sufficiently action-oriented; that is, when we are in a crisis, it is unclear who needs to do what and how the various agencies will co-ordinate their actions. In contrast, the best-in-class in the private sector develop action-oriented playbooks. For example, when event "X" happens, a specific playbook for "X" is activated that quickly sets up an organization & governance structure for coordination and response. Highly resilient organizations also develop the critical capability to create playbooks on the fly for events that are unanticipated. Within the public sector, exemplars of such capabilities include the US Department of Defense and the US Coast Guard. Unfortunately, such specificity is lacking in our current response frameworks and pandemic plans.

Furthermore, response capabilities discussed in NRFs are mostly focused on "service delivery" that cover provision of health services, evacuation, food & shelter, etc. Effective service delivery, however, assumes that we have the right products (e.g., medicines, equipment) to deliver the services. Missing is any discussion of product supply chains, assessment of its vulnerability, and need to build resilience in them. For crises that are local and book-ended in time, vulnerabilities in product supply chains are not visible and mostly inconsequential; after all California or Michigan can step up to address the needs of a crisis in Florida or Louisiana. But when the crisis is national / global and long lasting like this pandemic, vulnerabilities in product supply chains quickly become apparent and cripples a nation's ability to respond.

Vulnerabilities in product supply chains often show up as shortages. In the event of a shortage and demand for products from numerous entities, lack of coordinated action to secure supply leads to mass confusion, chaos, frustration, and unnecessary delays. For example, several manufacturers received orders for PPE and masks from multiple federal and state agencies as well as hospitals, but were unable to sort out if these were true requirements from distinct regions or multiple ordering to fulfill the same need. Not only was the size and scale of the demand and where the supplies were needed unclear, but it was also unclear which USG entity – HHS or FEMA – was responsible for coordinating the overall response.

Faced with shortages, the Defense Production Act (DPA) was activated for certain commodities, providing incentives to current manufacturers to scale capacity as well as recruit new manufacturers to step up to produce the much needed products (e.g., ventilators by General Motors). But the ability of manufacturers (incumbents or new) to scale up critically depends on availability and access to materials and components needed to produce the products. Rapid scaling of production becomes difficult without a deep understanding of vulnerabilities further

upstream in the global supply chains and timely actions to mitigate them. This is further impacted by geo-political actions of nation states that erected barriers for goods flow.

For new producers, speed of scale up may also be affected by their access to knowhow (e.g., product designs). Many small and medium advance manufacturing enterprises wanted to step in to fill the gap. Several were willing to make the needed investments to setup capacity and seek regulatory approvals for products if only they could get demand commitments that rarely materialized. Reasons for such lack of commitments are unclear, especially when shortages were persistent and severe. It is likely that they were too small to secure orders from large agencies; or that contracting processes of agencies were inflexible; or that health systems were not setup to onboard new suppliers and make advance commitments. States could have stepped in on behalf of healthcare providers to pool requirements and make commitments to activate supply but they did not. At the same time there was no clear regional / national picture of commodity needs of various health institutions – large and small. While some large health facilities might have had the capabilities to acquire goods on their own, non-hospital facilities were left in the lurch.<sup>6</sup> State agencies, who had little knowledge of global sourcing, scrambled to procure goods from anywhere in the world they could.

Causes of such shortages are numerous, including inadequate buffer / emergency stock, globally outsourced supply chains and vulnerability they have created, export restrictions, long lead times, lack of incentives to invest in capacity without clear visibility of demand, lack of firm commitments, etc. At the same time it is useful to remember that this pandemic created an unprecedented demand for these commodities across the globe, sometimes exceeding ten times the normal demand. No amount of buffer stock can meet such extreme requirements; neither are traditional supply chains designed to flex to such huge surges in demand. We need innovative approaches and solutions.

#### DEVELOPING PREPAREDNESS AND RESPONSE CAPABILITIES

Coordinating Agency: Living through the chaotic response to the pandemic often felt like we were in an orchestra without a conductor and sheet music. This is unacceptable. As we outline in the P2P-GSCTF report, it is imperative that only **one** organization plan and prepare for, coordinate, and respond to national disasters and emergencies. The pandemic, due to its longer duration and international systemic shock, exposed serious fault lines and it is imperative that we rethink our preparedness and response strategy. Accordingly we propose transforming the national response coordination center into the National Preparedness, Coordination & Response Center (NPCRC) that would collaborate across the whole of government to continuously monitor, prevent, prepare for, and respond to pandemics and other types of disasters maintaining a common operational picture across relevant organizations. Essentially NPCRC will be the conductor.

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<sup>6</sup> Shortage index data compiled by <https://getusppe.org/data/>

Supply Chain Institute: The work of NPCRC has to be supported with research on global supply chains and advice on preparedness and response strategies. In our P2P-GSCTF report, we propose a Supply Chain Institute (SCI), necessary to create comprehensive solutions and strategies to address supply chain vulnerabilities for critical goods. The proposed SCI, a bureau within the Department of Commerce (DOC) and complementing other national initiatives in manufacturing (please see detailed P2P-GSCTF report), will be a **national research & vigilance body** focusing on all sources of the dynamically evolving supply chain risk landscape, perform vulnerability assessments, recommend mitigation actions, provide regular reporting, and play an advisory role to NPCRC on supply chain matters of national security and public health response. Given the cutting edge and complex nature of the issues involved, the SCI should leverage expertise from academia and other institutions – public and private. Some of the capabilities within the SCI should include:

- Global Supply Chain Mapping: It is hard to navigate without a map of the extended supply chain. Mapping is critical to assess vulnerabilities and take necessary actions, ex-ante to mitigate risks for better preparedness and ex-post for rapid response.
- Develop methods for demand assessment: Without a good understanding of demand for needed critical goods like PPE, masks, etc., it is hard to assess adequacy of capacity. Yet, users (health and non-health facilities) do not routinely share such demand information; during a crisis it is even harder to elicit true demand. In a correspondence recently published in *The Lancet*, my co-authors and I outline a four-step framework that includes a smart sampling approach to such consumption data gathering on a routine (pre-disaster) basis. Converting such consumption data to need during a pandemic / disaster will, in addition, require sophisticated modeling using a multi-disciplinary (e.g., epidemiologists, behavioral scientists, supply chain experts) approach to project demand over time and develop various scenarios.<sup>7</sup>
- Perform resiliency analysis of the supply chain: Multiple factors impact the resiliency of global supply chains. However, speed of response in a crisis is of essence. Thus a measure resiliency could be the time taken to increase capacity by a desired amount; lesser the time taken, the more resilient the supply chain. The objective will be to develop recommendations on supply chain structuring to deliver on desired resiliency goals determined in consultation with NPCRC.
- Develop and recommend mitigation actions: The SCI will develop recommendations for mitigation actions (e.g., buffer stock, surge capacity, etc.) to achieve resiliency targets as well as advice NPCRC on rapid response; I elaborate more on this in the preparedness section that follows.

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<sup>7</sup> He, S. Bala, R., Anupindi, R., and Ranney M., “Effective supply chain surveillance for PPE”, *The Lancet*, Correspondence, Volume 397, Issue 10286, p1706-1707, May 08, 2021

- Develop and maintain risk and response playbooks: Plans are of little use if we cannot execute them. Plans by nature assume an anticipated state of the world. But actuality may significantly differ from this anticipated state. Unless there is routine evaluation (via, say, drills), we do not know whether we can execute. Playbooks and drills are critical to identify gaps, take corrective actions, and maintain readiness.

Preparedness: We cannot stockpile our way out of crises. Most discussions of preparedness mention the Strategic National Stockpile (SNS), how it fell short of expectations during this pandemic, and recommendations on how to improve its functioning. Improving SNS is necessary and SNS2.0 is already under development. However, I believe that while stockpiling is important it is an insufficient instrument for preparedness. We also need surge capacity. Leveraging the capabilities of our friendly trading partners, we should aim to develop a global / regional / local diversified and distributed production network for critical medical commodities. Domestic production should be an element of resiliency but exclusive reliance on it is risky and inefficient. Manufacturers who are willing to invest in resiliency by building surge capacity need to be compensated through preferred purchase contracts possibly compensated with a resiliency premium price. Even so, incumbent capacity may be insufficient. Other companies with process capabilities could be asked to supply products by activating the DPA, as we did. *But a core part of preparedness has to include ex-ante identification of firms that have the process capabilities to step up.* Even when these companies have the process capabilities, their ability to execute and deliver quickly will critically depend on having access to product designs and supply of requisite components and materials. So ex-ante supply chain analysis to assess and identify firms with product and process capabilities to quickly respond when needed will be essential. *This line of thinking suggests a broader interpretation of a “stockpile strategy” to include storage of products and critical components / materials, maintaining a library of firms with process capabilities to activate and product licenses to share as needed, and enabling these with appropriate incentives for the relevant actors.* Furthermore, such capabilities can be significantly enhanced by digitization<sup>8</sup> of product designs, processes and supply chains.

Other strategies for better preparedness and resiliency would include contracting flexibility to quickly onboard new, especially advanced manufacturing SMEs, would be essential. The United States has deep manufacturing expertise, which should be expanded, and mechanisms developed to activate them quickly. Innovative financing and advance market commitments were successfully used under Operation Warp Speed to achieve the unthinkable of getting successful vaccines to market in record time; similar mechanisms should be explored for production of other medical commodities as well.

While upstream product supply chain has been much of the focus of discussions in the context of preparedness and response, I will be remiss not to highlight the importance of readiness of the downstream supply chain from manufacturers to service delivery points (e.g., health facilities) both public and private. In our study of COVID-19 testing we found that the information

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<sup>8</sup> Please see the digital twin idea in the P2P-GSCTF report.

systems capabilities and interoperability of many facilities was severely deficient. Their just-in-time procurement strategies left them with little buffer stock. Expecting and incentivizing them to maintain a buffer stock of consumables should be part of a preparedness plan. Sourcing and supply chain processes of health systems are unsophisticated and not focused on resiliency; for example, many do sole sourcing based on lowest cost leaving them vulnerable to disruptions. They need to be nudged to adopt more resilient sourcing strategies.

Finally, the private sector has deep capabilities to manage global supply chains. We need to create structures to leverage such human resource expertise in times of crises to help manage our response supply chains.

### CONCLUSION

According to the Global Health Security Index<sup>9</sup> we were ranked as the best prepared nation in the world to deal with a pandemic. This turned out not to be so. The COVID-19 crisis has exposed serious gaps in our response. I believe the missing link was a coordinated and well-orchestrated process connecting the various elements of the end-to-end health commodity and service supply chains necessary for rapid and effective response.

It is heartening to see that the Biden administration has ordered multiple 100-day studies of some critical supply chains. I am certain that these will be very useful and a good first step. Global supply chains, however, are dynamic affected by technology shifts, geopolitical developments, evolving industry dynamics, changing health landscape, and emerging threats. Therefore we need a *sustained* effort to monitor supply chains for preparedness and response. It is imperative that we maintain situational awareness that calls for a surveillance mindset. As an analogy, we could look at approaches to maintain stability of global financial systems. Global (e.g., IMF) and national (e.g., Federal Reserve) agencies maintain surveillance, formulate policies (e.g., maintaining liquidity) and perform stress tests to ensure stability of financial systems. We need to evolve similar strategies for disaster preparedness and response. This could take the form of using a resiliency index (to be developed) to measure preparedness and response capabilities of the various actors across the end-to-end supply chain including public agencies. We need a single point of responsibility that is supported by proper governance structures to ensure preparedness and rapid response. We also need to ensure sustained funding for developing the suggested capabilities. Eternal vigilance is the price we have to pay for preservation of Life, Liberty and Pursuit of Happiness.

Thank you for the opportunity to share my thoughts in this statement. I hope you will find it useful in your investigations. I welcome the opportunity to work with the Committee in the future as you develop mechanisms to help the country develop more robust preparedness and response capabilities in our supply chains for effective and rapid response to protect and lives and livelihoods.

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<sup>9</sup> <https://www.ghsindex.org/>



May 27, 2021

The Honorable Gary Peters  
724 Hart Senate Office Building  
Washington, DC 20510

The Honorable Rob Portman  
448 Russell Senate Office Building  
Washington, DC 20510

**RE: Supply Chain Recommendations**

Dear Senator Peters and Senator Portman:

ASHP has long advocated for aggressive policy actions to strengthen supply chains and increase transparency in the U.S. and global regulatory system. In 2020, we convened a [July 2020 joint summit](#) examining the resilience of the U.S. pharmaceutical supply chain in light of the current state of global pharmaceutical manufacturing. The 2020 summit proceedings, which build on findings from a similar [2018 joint meeting](#), include a number of findings and recommendations that heavily informed the shortage provisions in the Coronavirus Aid, Relief, and Economic Security (CARES) Act and that we believe would be valuable to you during the 100-day review required by the EO.

ASHP is the collective voice of pharmacists who serve as patient care providers in hospitals, health systems, ambulatory clinics, and other healthcare settings spanning the full spectrum of medication use. The organization's nearly 58,000 members include pharmacists, student pharmacists, and pharmacy technicians. For 79 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety. For more information about the wide array of ASHP activities and the many ways in which pharmacists advance healthcare, visit ASHP's website, [ashp.org](http://ashp.org), or its consumer website, [SafeMedication.com](http://SafeMedication.com).

To assist in the Committee's work to address drug supply chain challenges, ASHP has developed the following initial recommendations:

1. Require FDA to provide ratings of the quality management processes of drug manufacturers that are predictive of supply chain and manufacturing vulnerabilities.
2. Expand the Drug Supply Chain Security Act (DSCSA) to require manufacturers to provide transparency in API sources and manufacturing locations, including locations of contract manufacturers.
3. Identify key starting materials, active pharmaceutical ingredients, and finished dosage forms of essential medicines that should have domestic manufacturing capacity to improve the resilience of the U.S. drug supply, and incentivize their production without limiting access to foreign sources of product.
4. Improve the functioning of the Strategic National Stockpile (SNS) by:
  - a. Finalizing and regularly updating a list of medicines necessary to respond to potential national-scale public health emergencies, which should be included in the SNS. These drugs may differ from those on the essential medicines list.
  - b. Increasing transparency regarding the specific products and quantities of such products included in the SNS.
  - c. Publishing a clear, nationally consistent process for making requests from the SNS, including publication of contact information for key personnel in each agency that has responsibility for the managing requests and distributions from the SNS.

- d. Engaging pharmacists and other supply chain experts to develop process for maintaining and refreshing products in the SNS.
- e. Creating a standard distribution logistics process for medications and related supplies from the SNS, that incorporates feedback from pharmacists and other supply chain experts, including clear expectations for how updates to these processes will be publicized, if needed, in the event of a national emergency.
- f. Publishing criteria that will be used to prioritize distribution of products from the SNS, including clear expectation for how updates to these criteria will be publicized, if needed, in the event of a national emergency.
- g. Incentivizing the creation of a private sector reserves of essential medicines not adequately provided by the SNS.

ASHP is also collaborating with a group of healthcare organizations to develop additional consensus recommendations on a number of supply chain issues, including quality and manufacturing improvement (e.g., reducing contamination in finished pharmaceuticals) and medical supply and medical device supply chain reinforcement.

We would welcome the opportunity to meet with you to share these recommendations, which are drawn from our members' expertise and their real-world experience with utilizing complex, and often delicate, medical supply chains.

Sincerely,

A handwritten signature in black ink, appearing to read 'Tom Kraus', with a stylized, wavy underline.

Tom Kraus  
Vice President of Government Relations  
ASHP (American Society of Health-System Pharmacists)



May 19, 2021

Members of the U.S. Senate Committee on Homeland Security and Governmental Affairs:

On behalf of BioOhio and our 300+ members that employ over 100,000 Ohioans in the bioscience industry, I am honored to submit a statement for today's hearing "*COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps*." BioOhio is a non-profit organization that connects and serves Ohio's bioscience community — medical device, diagnostic testing, drugs and pharmaceuticals, digital health and agricultural biotechnology — to drive success in improving global quality of life. Since 1987, we have represented a statewide ecosystem that ranges from the individual entrepreneur to some of the largest companies in the world, health systems and all the professional service providers and supply chain necessary for a company to grow. As we have learned through this pandemic, a supply chain that is mostly operated outside of the United States can be detrimental in a public health emergency.

BioOhio strongly supports the onshoring and reshoring of personal protective equipment (PPE) as well as access to quicker and accurate testing. I would like to share Ohio's bioscience landscape and how it fits into the greater U.S. picture for surveillance, testing, diagnostics, PPE manufacturing, etc. and offer some specific suggestions we believe officials should take to correct failures for the future and improve our pandemic preparedness. Ohio remains a strong bioscience manufacturing state and is particularly strong in medical device and diagnostics. Three examples of the numerous Ohio companies that provided critical products during the pandemic are:

[Quidel](#) — Manufacturing in Southeast, Ohio, Quidel operates at the forefront of the battle against the coronavirus pandemic. Quidel received Emergency Use Authorization (EUA) from the FDA for its Lyra® SARS-CoV-2 Assay, a real-time RT-PCR test intended for the qualitative detection of nucleic acid from COVID-19 on March 17, 2020. Lyra® is a leading molecular test for COVID-19. On May 8, 2020, Quidel was first to market in the U.S. with a rapid antigen test that delivers results in 15 minutes. Quidel's Sofia® SARS Antigen FIA set the bar for antigen test accuracy, proving to be in agreement with PCR results 96.7% of the time.

[Meridian Biosciences](#) — Based in Southwest, Ohio, Meridian Biosciences is a provider of diagnostic testing solutions and life science raw materials. In January 2020, Meridian Biosciences stock price went up because of their product called Lyo-Ready 1-Step RtaPCR Mix. In layman's terms, the mix is a screening kit for Coronavirus. But it's not just that — it's a screening kit that's faster and cheaper than most of its competitors, of which there are few to begin with. Skipping to February 2021, Meridian announced that it will increase production capacity of the company's SARS-CoV-2 molecular diagnostic test on its Revogene® platform after receiving a \$5.5M award from the National Institute of Health (NIH) Rapid Acceleration of Diagnostics (RADxSM) initiative and an additional grant from JobsOhio.

[GOJO](#) — Based in Northeast, Ohio, their most visible product is PURELL. Adding two more sites in Ohio in 2020-2021, bringing the company's Ohio manufacturing facilities to four, GOJO employs more than 2,500 team members around the globe and is expecting to add at least 200 jobs with these two additional Ohio facilities.

These are just three of the many Ohio bioscience companies that stepped up during the pandemic to enhance our state-wide and national response. We have more than 500 medical device and diagnostic companies that also played a role in the response which can be found [here](#) at the BioOhio Bioscience Resource Directory, accessible and searchable 24/7. We are proud of Ohio's bioscience innovation and manufacturing prowess during this crisis as well as year-round in producing countless, life-saving and life-altering medical innovations. We can play an even bigger role in U.S.-made products and that is why we support the onshoring and reshoring of personal protective equipment (PPE) as well as access to quicker, accurate COVID testing.

Manufacturing support systems in Ohio are distinctive. The [Ohio Manufacturing Alliance \(OMA\)](#) is guiding manufacturers to help them learn what types of equipment are most needed and how to adapt current products, operations and personnel to meet the need. Ohio Manufacturing Extension Partnership (MEP), with its partner organization [MAGNET](#) in a lead role, is providing engineering capabilities and technical support to make PPE alternatives when possible. OMA is managing outreach to manufacturers, and Ohio Hospital Association and nursing homes are providing insights on the products most needed. Another key source of economic growth in Ohio, JobsOhio, is a private nonprofit economic development organization that helps businesses relocate, expand and prosper in Ohio. It is providing regional support and financial assistance, where appropriate, to accelerate production and build on the OMA and MAGNET assets.

With regard to the National Stockpile, Ohio is uniquely situated as a state both in geographic location and assets that make it notable. More than 59.9% of the U.S. population lives within a 600-mile radius of Ohio and can reach the state in about 8-9 hours. Additionally, the Defense Supply Center located in Columbus, is one of three Inventory Control Points of the Defense Logistics Agency, a major material passthrough. We also hold the Air Force Research Laboratory in Dayton, which is a consolidated US Air Force medical command, and NASA Glenn and NASA Plum Brook in Northeast Ohio where innovative Medical Research and Technology projects continue to shape healthcare. Thus, bridging our innovation and manufacturing capabilities with our geographic location makes Ohio the ideal state to lead in U.S. supply chain production.

In closing, there are some important steps that government can take to improve our pandemic preparedness, such as:

- **Create an IRS Tax Code that is more globally competitive.**
- **Implement incentives to reshoring manufacturing focused on PPE and pandemic related needs.**
- **Expand or make permanent the R&D tax credit.**
- **Maintain strong intellectual property rights.**
- **Establish Workforce Training Grants for companies expanding capacity in the PPE related space or shifting their traditional manufacturing to the bioscience industry.**

With more investments and a more competitive environment, the bioscience industry can be better prepared for future pandemics and we can ensure that, should this happen again, our supply chain is robust and more rooted here in the U.S. Please do not hesitate to contact me personally at [jlewis@bioohio.com](mailto:jlewis@bioohio.com) with any questions.

Sincerely



John F. Lewis Jr.  
President & CEO, BioOhio



✉ [admin.info@state.mn.us](mailto:admin.info@state.mn.us)

📍 50 Sherburne Ave.  
St. Paul, MN 55155

📞 651-201-2555

May 17, 2021

The Honorable Gary C. Peters, Chairman  
U.S. Senate Committee on Homeland Security  
& Governmental Affairs  
340 Dirksen Senate Office Building  
Washington, DC, 20510

The Honorable Rob Portman, Ranking Member  
U.S. Senate Committee on Homeland Security  
& Governmental Affairs  
340 Dirksen Senate Office Building  
Washington, DC, 20510

Dear Chairman Peters and Ranking Member Portman,

Thank you for the opportunity to submit a statement for the record for the Senate Homeland Security and Governmental Affairs Committee (HSGAC) upcoming hearing, *COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps*.

I serve as the Commissioner of the Minnesota Department of Administration. Since March 2020, I have led the State of Minnesota's efforts to secure Personal Protective Equipment (PPE).

As the world began to witness the onset of a new pandemic in early 2020, the State of Minnesota opened its State Emergency Operations Center and implemented emergency preparedness plans. Such planning and response coordination at the federal, state, and local levels of government has been standard operating procedure in previous pandemics. What was absent in early 2020 was a coherent strategy from the federal government, which caused each state to replicate emergency purchasing operations that began competing with one another for already scarce medical supplies.

In March 2020, the State of Minnesota established the Critical Care Supplies Work Group to source the PPE needed for front line healthcare workers. I led this core team comprised of a small, interagency, interdisciplinary group comprised of a project manager, a procurement professional, a data analyst, and two logisticians. Collectively, this group was responsible for securing masks, face shields, gowns, gloves, N95 respirators, as well as ventilators and source protection such as cloth masks, thermometers, and hand sanitizer.

The State of Minnesota immediately began working with its traditional vendors and supply chains. We knew these trusted partners could be depended on because of past relationships and volume purchases. Given the international and domestic competition for scarce PPE, however, the State had to quickly establish additional supply chain partners. The State created a portal for potential vendors to submit solicitations, which soon became overwhelmed with both legitimate and fraudulent offers. The State refined screening procedures that allowed the small team to concentrate on offers from legitimate businesses and leveraged the expertise of MMCAP Infuse, a division of the Minnesota Department of Administration, that contracts for pharmaceutical and medical supply businesses on behalf of public institutions in all 50 states.

Minnesota is blessed with an incredible corporate community that stepped forward in this time of crisis to share its expertise with the State. The companies allowed us to leverage their relationships, their resources, their supply chains, and their transportation networks. Corporate partners such as Ecolab, 3M, Medtronic, Mayo, Donaldson, CH Robinson, Target, Patterson, Toro, and Medical Alley shared sourcing networks around the world, coupled with supply chain, logistics, and inventory expertise.

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Page Two

These companies have used their international presence to validate factory production, test products, and take photographs of products for our review. These local corporate partners left Minnesota in an enviable position relative to other states and we are grateful for their efforts to ensure that Minnesota had any advantage they could help provide in the fight against COVID. These companies and individuals have been generous with their time, their talent, and their teams.

Another key tool in this effort was the data analysis and forecasting tool we developed to predict PPE usage or "burn rates" statewide. This involved a daily calculation of total state inventory, the average daily usage rate over a rolling ten-day period, and warehouse availability of PPE. Since the duration and the severity of this event were unknown, we further planned for high, medium, and low usage scenarios, as well as a 12-, 16- and 20- week event.

This information was critical to determining volume and prioritization of PPE needs to be purchased by the State. Healthcare providers are responsible for maintaining their own supply chains, therefore the PPE purchased by the state is intended to be supplemental. As hospitals and clinics reach low inventories, they can requisition the State for quantities to bridge their inventory shortfalls. The State warehouse initially required hospitals to be in crisis inventory situations, meaning they had only 0-3 days of supply, before the state would fulfill their PPE requisitions. With the establishment of a more stable supply chain, requisitions are filled when they reach a less critical 4-7day inventory. The State has also been able to expand the types of entities receiving PPE, e.g. long-term care facilities, clinics, homeless shelters, schools, and daycares.

The State of Minnesota also utilized PPE from the federal government's Strategic National Stockpile (SNS) as it became available. Materials from the stockpile supplemented the supplies that our purchasers were able to independently procure. Two key problems emerged with federal supplies. The first was the unpredictability of what the SNS would supply and when supplies would arrive. The initial lack of information regarding access to ventilators and how the SNS would help states procure them is well documented. Second, some of the supplies were either not medical grade or simply were poorly manufactured. For example, shipments of respirators did not meet 95% filtration specifications or medical gowns that were received did not have arm holes.

Despite the challenges of intense competition and supply shortages, the State of Minnesota created a successful PPE operation that has been able to support health care facilities across the State. The State's warehouse is now stocked with enough PPE including gowns, gloves, N95s, surgical masks, and face shields to handle an extreme surge. We also have a supplemental supply of ventilators now available for future emergencies.

Again, thank you the opportunity to submit an overview of the State of Minnesota's experience in procuring PPE during the height of the COVID-19 pandemic.

Sincerely,



Alice Roberts-Davis  
Commissioner



**Statement for the Record  
On Behalf of Henry Ford Health System  
To the United States Senate Committee on Homeland Security and Governmental Affairs  
"COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps"  
May 19, 2021**

Chairman Peters, Ranking Member Portman, and distinguished Members of the Senate Committee on Homeland Security and Governmental Affairs, thank you for your leadership in addressing the current COVID-19 pandemic and considering ways to improve the medical supply chain for current and future public health emergencies (PHEs). Henry Ford Health System (Henry Ford) is appreciative of the opportunity to share our perspectives on hospitals' efforts to obtain critical personal protective equipment (PPE) and medical supplies during the COVID-19 PHE.

Henry Ford is a Michigan-based, non-profit, integrated health system committed to improving people's lives through excellence in the science and art of healthcare and healing. Henry Ford offers healthcare services across the continuum of care through a diverse network of facilities in Southeast Michigan (Metro Detroit) and South-Central Michigan (Jackson). The system includes five acute-care hospitals; an inpatient psychiatric facility; and a network of outpatient medical facilities staffed by members of the Henry Ford Medical group (HFMG). HFMG includes more than 1,900 physicians and researchers practicing in more than 50 specialties. Henry Ford is one of the nation's leading academic medical centers and provides health coverage for more than 540,000 people through our not-for-profit health plan, Health Alliance Plan.

For more than a year, Henry Ford has been on the front lines of the COVID-19 pandemic, serving some of the hardest hit areas of the state. To date, the health system has treated more than 44,000 patients with COVID-19 and administered more than 310,000 doses of the vaccine. In addition to providing treatment, we continue to work with local and state organizations to offer COVID-19 testing, administer vaccines through our mass vaccination sites and mobile clinics, and educate patients and our communities on the 2019 novel coronavirus and COVID-19 vaccines as we work to end the PHE.

Like many hospitals and health systems across the country, Henry Ford has faced challenges throughout the COVID-19 PHE in acquiring key equipment that medical staff need to care for critically ill patients, including PPE (e.g. medical/surgical masks, gloves, face shields, gowns, N95 respirator masks, and hand sanitizer), ventilators, COVID-19 testing kits, and pharmaceuticals. Shortages have occurred throughout the pandemic when our normal distribution and contracted supply channels were grossly overwhelmed with demand, leading them to frequently stock out of critical supplies.

Without proper equipment, our healthcare workers, patients, and visitors are put at risk of virus exposure, and without proper medical supplies, we cannot treat our patients effectively and safely. In response to the shortages, Henry Ford was forced to seek PPE from local businesses and manufacturers that had extra supplies, rely on health systems in other markets that were experiencing fewer COVID-19 cases, and ultimately pursue gray market options for critical supplies. This unofficial supply channel was

an inadequate source for supplies, as we found that many entrants into the gray market were price gouging, selling fraudulent supplies, or simply unable to deliver on promises. Our supply chain, having limited international shipping and logistics expertise, struggled to navigate the global supply chain to acquire direct supplies from international sources. This resulted in Henry Ford, and many other states and health systems, competing against others across the country to source and distribute limited supplies from the national stockpile and manufacturers.

Many factors contributed to these shortages. Prior to the PHE, the healthcare supply chain had forced lower market prices, requiring original equipment manufacturers to consolidate manufacturing for scale and outsource to foreign markets in search of the lowest costs (and highest quality) goods. As a result, many PPE supplies, such as face masks, are produced abroad, leaving the United States vulnerable to global supply chain disruptions. In addition, primary distributors in healthcare have been leaning out inventory for years to reduce the inventory cash liability. These factors, combined with the entire industry failing to diversify their risk in their supply portfolio (e.g., manufacturing sources and raw material sources), contributed to extreme shortages when the pandemic struck. Shortages were also exacerbated by an insufficient stock in the national stockpile and variation between states in stockpiles and emergency management supports, leaving many organizations to fend for themselves during the PHE to acquire critical supplies.

We thank Congress for the support provided through the COVID-19 relief packages. The Coronavirus Aid, Relief, and Economic Security Act, in particular, has substantially helped Henry Ford with our ability to purchase safe supplies. Since the early days of the pandemic, Henry Ford has taken many steps to ensure we have adequate supplies for the safety of our team members and community now and in the future. For example, the Henry Ford Innovations Institute has developed creative solutions to rapidly produce high-quality PPE by working with local manufacturers. We have also established PPE utilization standards, enhanced inventory management practices for PPE, diversified our supply portfolio to multiple manufacturers, and invested in domestic glove, mask, and gown manufacturers.

Going forward, improvements could be made to ensure a robust and effective PHE response via a well-managed supply chain and logistical operation. The strategy should utilize existing laws and regulations, such as the Defense Production Act, to direct private companies to produce equipment needed for a national emergency, and create new ones, where needed, to ensure preparedness at all levels. Some actions that the federal government could take include:

- Maintaining a larger national stockpile of PPE, ventilators, and other durable medical equipment for current and future PHEs
- Requiring data transparency of manufacturing and raw material sources to allow organizations, such as Henry Ford, to better risk score supply portfolios
- Incentivizing domestic manufacturing as part of the solution to mitigate risk in supply portfolios
- Providing financial subsidies to assist organizations, including Henry Ford, in PPE purchase costs and utilization increases

In addition to ensuring supply chains remain open for drug and device access, it is critical that a network is created among agencies and organizations to share information and supplies as they are needed

across the country. Federal organizations, such as the Centers for Disease Control and Prevention, Food and Drug Administration, and Department of Health and Human Services could engage with medical device and pharmaceutical industries, health systems, and other emergency response organizations to coordinate efforts and communication across industries, which is key to success moving forward.

Thank you for the opportunity to provide input on this important matter. Henry Ford has a robust network of hospitals, medical facilities, providers, and researchers that are willing and able to engage in efforts to ensure we are better able to prevent, prepare for, and respond to future pandemics.



Statement for the Record

Matthew J. Rowan

President and CEO

Health Industry Distributors Association

On

“COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps”

Before

Senate Homeland Security and Governmental Affairs Committee

May 19, 2021

Thank you Chairman Peters and Ranking Member Portman for today's Senate Homeland Security and Governmental Affairs Committee hearing, "COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response." This hearing can help identify lessons learned from this pandemic and a path forward for future preparedness.

The Health Industry Distributors Association (HIDA) supports policies **bringing the best of the public and private sectors together to establish long term preparedness solutions.** Together the private sector and public sector possess the scope of capabilities, infrastructure, funding and expertise to prepare and respond to public health emergencies in the United States.

Attached is HIDA's white paper, "Building A More Robust Supply Chain: A Public-Private Framework to Create A Pandemic Response Infrastructure." Our white paper outlines steps to strengthen our medical products supply chain. To do this effectively, the public and private sectors must work together to:

1. Make the supply chain more robust, utilizing the nation's 500 commercial distribution centers to forward deploy critical products
2. Diversify sourcing
3. Expand and support surge manufacturing capacity
4. Prevent development of a fraudulent opportunistic marketplace

This framework informed bipartisan legislation, The Medical Supplies for Pandemics Act, introduced in the Senate last year and being reintroduced this year. The Medical Supplies for Pandemics Act strengthens the public/private partnership between the Strategic National Stockpile (SNS) and the commercial supply chain. **We urge all members of the Committee to cosponsor the legislation.**

The bill includes the following provisions which together will significantly enhance our nation's ability to successfully manage future pandemics.

1. **Diversify Production:** Directs SNS to work with manufacturers to diversify medical supply manufacturing.
2. **Invest in Capacity:** Directs SNS to work with manufacturers on innovative ways such as joint ventures to ensure capacity levels can robustly ramp to meet surge demand.
3. **Partner with Distributors:** Directs SNS to partner with commercial distributors to manage a cushion of critical pandemic supplies such as PPE, testing supplies, ancillaries, and infection prevention products to prevent expiration and waste.

Throughout this pandemic, medical products distributors collaborated with the federal government as trusted partners. Every day, our distributors utilize their existing infrastructure to reliably deliver essential medical supplies the last mile into the hands of providers. HIDA members applied their expertise and infrastructure to move a record 51 billion units of PPE through the supply chain to healthcare providers in 2020. This included a 1200% increase in N95 respirators, 150% increase in face masks, 36% more gowns, and 11% more gloves.

Our nation's more than 200 medical products distribution companies provide logistics expertise essential to handling 650 million orders every year. Our vast distribution network reaches

provider locations across all care settings. This includes: 6,000 hospitals, 15,600 nursing homes, 28,900 assisted living facilities, 12,200 home health agencies, 267,000 laboratories, and 230,000 physician offices and clinics.

HIDA appreciates the important work being done in your committee. We look forward to working with you on long-term policy solutions. Please reach out to HIDA's Vice President of Government Affairs, Linda Rouse O'Neill at [Rouse@HIDA.org](mailto:Rouse@HIDA.org) with any questions.

Sincerely,

A handwritten signature in black ink that reads "Matthew J. Rowan". The signature is written in a cursive style with a large, stylized initial "M".

Matthew J. Rowan  
President and CEO  
Health Industry Distributors Association (HIDA)

**Building A More Robust Supply Chain:  
A Public-Private Framework To Create  
A Pandemic Response Infrastructure**

September 2020



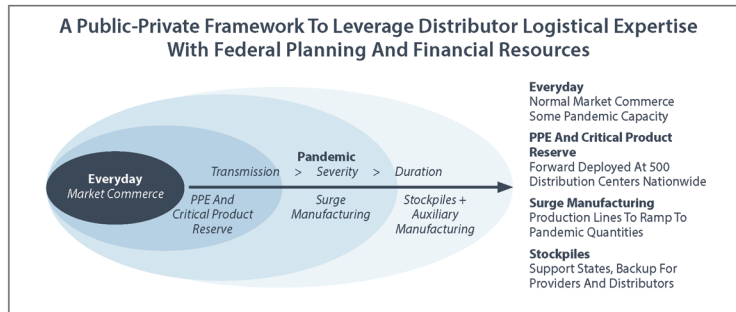
## Executive Summary

To prepare for the next pandemic event, the U.S. must strengthen its health industry supply chain by creating a pandemic response infrastructure that can both meet an initial, massive surge in demand for key medical products and ramp up quickly to replenish the supply chain continuously over a sustained period of time.

The U.S. healthcare supply chain is strong, but the COVID-19 pandemic demonstrated it needs to be more resilient. Policymakers, manufacturers, group purchasing organizations, and distributors have learned they need to work together to 1) make the supply chain more robust, 2) diversify sourcing, 3) expand and support surge manufacturing capacity, and 4) prevent development of a fraudulent opportunistic marketplace.

The foundation of the pandemic response infrastructure should be a public-private partnership built on four pillars:

- **Forward-Deployed Personal Protective Equipment (PPE) And Critical Product Reserve:** Create stocks of federally funded and controlled pandemic supplies using the 500 commercial distribution locations throughout the U.S., positioning inventory close to healthcare providers and designed to meet their "first-call" needs for 30-60 days until surge manufacturing capability can be mobilized
- **Diversified Surge Manufacturing Capability:** Significantly expand U.S. and nearshored manufacturing capacity to establish a more strategic blend of sources capable of surging to increase volume in 30-60 days to keep customers and stockpiles supplied during a pandemic
- **Sustainable And Replenished Stockpiles:** Require centralized stockpiles to be replenished by the surge manufacturing infrastructure to support state and local government needs during a crisis and serve as a backstop to the commercial supply chain
- **End-User Aligned Supply Chains:** Align distribution channels to categories of end users to avoid surge-driven competition for products that drives up prices and encourages profiteering brokers to enter the marketplace



Only the coordinated and combined efforts of manufacturers, distributors and policymakers can build and support the pandemic response infrastructure the U.S. needs.

## Lessons Learned

The U.S. healthcare supply chain is strong, but the COVID-19 pandemic demonstrated it needs to be more resilient to respond to a sudden and massive increase in demand for medical products. The country continues to battle a disease that has now stricken two million people and caused more than 180,000 deaths in the U.S. as of August 2020. But manufacturers, distributors, group purchasing organizations, healthcare providers and policymakers have already learned at least four valuable lessons:

- 1) The supply chain must be more robust
- 2) Sourcing must be more diversified
- 3) Surge manufacturing infrastructure must be expanded and supported
- 4) Supply chains must be aligned to end users

### The Supply Chain Must Be More Robust

**A Lean Supply Chain Delivery Model That Helps Bend The Cost Curve:** During the regular course of business, the U.S. health industry supply chain does an efficient job of sourcing, shipping, storing and delivering thousands of healthcare products for 300,000 hospitals, nursing homes, home health agencies and physician offices. It relies on a just-in-time delivery principles pioneered by Japanese automakers and uses lean supply chain principles to keep manufacturing and inventory costs low. This helps bend the cost curve for healthcare by closely matching supply with demand to drive high efficiency when shipping, storing and managing large amounts of inventory. The model has some excess capacity built in to accommodate fluctuations in demand for products and anticipated events such as seasonal influenza, but significant and sustained changes to either the supply of products or the demand for them can lead to large disruptions.

**Unprecedented Surge In Demand:** The COVID-19 outbreak created a simultaneous and unprecedented global surge in demand for healthcare supplies. The Pentagon estimates that the demand for N95 respirators soared to 140 million masks during the 90-day peak of the pandemic. That is nearly three times the normal annual consumption of 50 million masks in the U.S. and represented an 11-fold increase in normal three-month usage rates.

*The Pentagon estimates that the demand for N95 respirators soared to 140 million masks during the 90-day peak of the pandemic, an 11-fold increase.*

A survey conducted by the prominent group purchasing organization Premier at the beginning of the pandemic in March 2020 found that hospitals treating COVID-19 patients were using face shields at more than eight times their usual rate and consuming isolation gowns at five times the usual rate.

Estimated Surge Usage of PPE At Hospitals Treating COVID-19

Supply	Surge Need	Inventory on Hand (Without COVID-19 Patients)	Inventory on Hand (With COVID-19 Patients)
Face Shields	8.6x	3.7 days	3.3 days
Viral Swabs	6x	10 days	9.3 days
Isolation Gowns	5x	4.5 days	2.7 days
Surgical Masks	3x	3.6 days	2 days

Source: <https://www.premierinc.com/newsroom/press-releases/premier-inc-survey-as-covid-19-spreads-to-new-hotspots-hospitals-should-prepare-for-up-to-a-17x-surge-in-supply-demand>

Typical shipping times for some supplies from an overseas manufacturer to a healthcare provider's doorstep via ocean freight are 30-40 days. This unprecedented surge in demand led to a rapid depletion of available inventory.

**Unanticipated Disruption In Supply:** At the same time COVID-19-related demand was surging, manufacturing facilities in China, the single largest source of PPE in the world, were being shut down due to the pandemic. Wuhan, the epicenter of the Chinese outbreak and a major source of PPE supplies, was dormant for nearly three months. Other Chinese manufacturing centers were also shuttered for weeks. The result was a significant reduction of supply from the country that produces a major share of the PPE imported by the U.S.

**The Need For Greater Reserves:** The twin stresses of increased demand and constricted supply demonstrated the need for distinct approaches to day-to-day demands versus those caused by an exceptional event. For everyday needs, the supply chain delivers a large number of products reliably, efficiently and cost-effectively. At the same time, the U.S. also needs a pandemic-oriented infrastructure that combines government planning with the commercial supply chain to create and maintain larger reserve inventories that can mitigate sizable disruptions in the supply chain.

## Sourcing Must Be More Diversified

**The Supply Chain Is Global:** The U.S. health industry supply chain globalized during the last forty years. It did so to take advantage of the development of highly specialized, lower-cost manufacturing expertise outside the U.S. to bend the healthcare cost curve. While the U.S. maintains manufacturing capacity for many types of PPE and medical supplies and, in fact, exports healthcare products to other countries, it also relies on overseas sources for large amounts of its own supplies. Building on long-term relationships with vetted foreign manufacturers, distributors help control costs for healthcare providers while delivering high-quality, FDA-approved supplies and equipment.

**Globalization Has Led To Concentrated Sourcing:** The globalization of the supply chain also resulted in concentration of the supply manufacturing in several countries. For example, China is the source of 72% of the surgical masks, and 54% of the medical gowns imported to the U.S. But China is not the only example of concentration. Malaysia is the source of 65% of the world's medical gloves.

*Malaysia is the source of 65% of the world's medical gloves.*

**The Disadvantage Of Concentration:** As the outbreak of COVID-19 in China demonstrated, one disadvantage of concentration is that the local disruption of a manufacturing center's production capacity can have a global impact. Another disadvantage is that the reliance on transoceanic shipping leaves the U.S. health industry supply chain vulnerable to climate-related events and natural disasters such as hurricanes and earthquakes that can render key ports inoperable for lengthy recovery periods.

**The Need For Reshoring And Nearshoring To Provide A More Diversified Mix Of Sourcing:** Today's global supply chain exists because it enables healthcare providers to benefit from the economies of scale, specialized manufacturing processes and lower costs of overseas production. Many of the economic benefits of the global supply chain would be significantly diminished if all production were to be reshored to the U.S. or nearshored to the Americas. But the COVID-19 pandemic has demonstrated the logistical and strategic need to rebalance the dependence of the U.S. on distant sources and increase the share of sourcing done closer to home. Achieving this diversity in sourcing will require a significant expansion of U.S. and nearshore manufacturing capacity.

## Surge Manufacturing Infrastructure Must Be Expanded And Supported

**A Lean Supply Chain Means Limited Additional Manufacturing Capacity:** The efficiency of the health industry supply chain includes "flex" capability to meet a surge in demand, but production lines run at near capacity. Adding greater capacity involves a significant investment in new equipment and the time to build or expand existing facilities. It is difficult for manufacturers to invest in capacity knowing that demand quickly dissipates after a public health event. Developing greater manufacturing capacity is a key opportunity for the private and public sectors to partner.

**Overseas Sourcing Complicates Rapid Response:** Even without the COVID-19 related production shutdowns in China, the steep increase in demand for medical supplies would have significantly stressed the global supply chain due to the lengthy shipping times involved in moving products from manufacturing centers to the U.S. When equipment burn rates increase dramatically, 30-40 day shipping times make it difficult for the supply chain to keep pace.

**The Need To Create And Support Surge Capacity In The U.S.:** The overall lack of flex capacity in the global supply chain coupled with the complications created by 30-40 day shipping windows point to the strategic need for the U.S. to develop and support production infrastructure that it can ramp up quickly to meet its own surges in demand. The goal is to have surplus capacity that leaves the U.S. less vulnerable to supply disruptions or sudden increases in national and global demand.

*When equipment burn rates increase dramatically, 30-40 day shipping times make it difficult for the supply chain to keep pace.*

## Supply Chains Must Be Aligned To End Users

**Increased Demand, Decreased Supply Led To A “Wild West” Marketplace:** The combined impact of a drastic increase in demand and constricted supply led to a “Wild West” marketplace as healthcare providers sought far more supplies than usual. In addition, the pandemic brought in new, non-traditional customers for PPE: state governments, charities, and businesses such as grocery store chains and airlines who needed PPE just to provide essential services and stay afloat. All of them competed for the supplies that were available.

**Fly-By-Night Brokers Enter The Marketplace:** To complicate matters further, as distributors faced the challenge of securing supplies for their current customers, and trying to help additional customers find PPE, new fly-by-night brokers entered the marketplace. Although some of these brokers had noble intentions, most had no expertise or experience in healthcare supply chains. They sourced products of unknown quality from unknown vendors and auctioned those products to the highest bidder. In many cases, brokers did not physically deliver supplies to healthcare providers and, as numerous reports in the media have confirmed, sometimes the product they “sold” did not even exist.

**The Need For Supply Chains Aligned To End Users:** While there were many contributing factors to the opportunistic marketplace resulting from the pandemic, a recurring theme from providers and states was confusion as to where and how to access supplies. This frequently initiated counterproductive bidding wars among the federal government, state agencies, healthcare providers and other customers for the same supplies and was a major enticement to unqualified, opportunistic brokers to enter the market. A comprehensive preparedness system should align end users to specific supply chains so expectations and communication are clear.

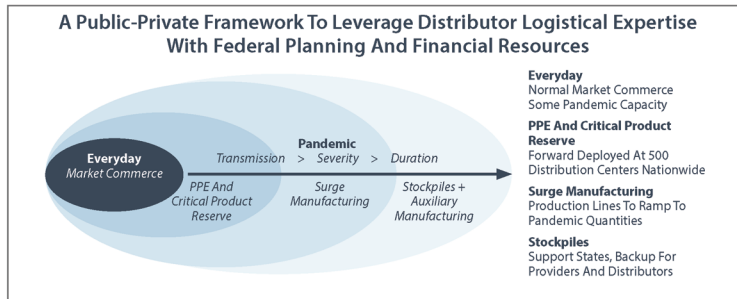
## The Response: A Public-Private Framework For U.S. Pandemic Preparedness And Response

The U.S. needs a national strategy that builds on the lessons learned from the COVID-19 pandemic. We must make available and continuously replenish medical products to satisfy massive, sustained demand from healthcare providers, consumers, first responders, states and essential workers.

This strategy must support, not supplant, the commercial supply chain. Planning should leverage private infrastructure to develop a “whole supply chain” effort. We must coordinate every global and domestic manufacturing source, medical distributor and distribution center in the U.S. to contribute in partnership with government agencies and planners before and during a pandemic.

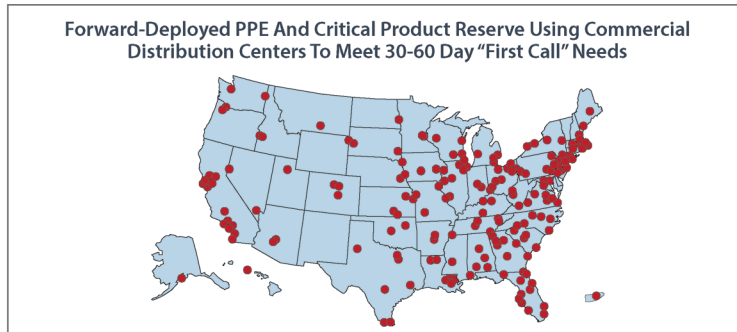
This infrastructure would feature four components:

- 1) A forward-deployed PPE and Critical Product Reserve
- 2) Diversified surge manufacturing capability
- 3) Sustainable and replenished stockpiles
- 4) End-user aligned supply chains



### Forward-Deployed PPE And Critical Product Reserve

**The First Line Of Defense:** The first line of defense against a future pandemic should include forward-deployed stocks of federally funded and controlled pandemic supplies in up to 500 commercial distribution locations throughout the U.S., positioning inventory close to every provider customer. Pandemic demand rises rapidly across the country and stresses the supply chain from the outset. By instinct and design, healthcare providers make their first calls for additional supplies to the distributors with whom they have long-term, proven relationships.



**A 30-60 Day Buffer:** The reserve would serve as an important buffer for Strategic National Stockpile supplies and allow sufficient time for surge manufacturing facilities (described below) to come online. While the exact amount and types of supplies would be determined by government planners in coordination with commercial market representatives, the goal would be to have 30-60 pandemic-level days of key supplies in the reserve. This would meet the most immediate needs of healthcare providers during a pandemic. Contract stipulations could include appropriate rotation to manage expiration dates, data linkages, and replenishment, among other terms, similar to the arrangements many states and healthcare providers currently have with distributors.

**Products In The Reserve:** While PPE would be at the core of the reserve, it should include all critical products needed during a pandemic response such as needles and syringes, infection prevention products, testing products, respiratory products, and IV solutions. During the current COVID-19 outbreak, distributors have identified 30-40 products for which demand spiked precipitously as the pandemic struck and lengthened.

**Reserves Should Meet Needs Of All Healthcare Providers:** A single distribution center serves dozens of very large customers and up to thousands of smaller to mid-sized healthcare providers such as physician offices, nursing homes and emergency medical services (EMS), among others. When determining the size of the forward-deployed reserves, planners should take into account that in the case of a pandemic, smaller, non-acute care providers will need PPE that they may not use during the normal operations.

## Diversified Surge Manufacturing Capability

**A Strategic Mix Of Domestic And Global Sources:** As discussed above, cost considerations, the ready supply of raw materials, economies of scale, and other factors have all contributed to the globalization of the supply chain. It would be impractical and cost-prohibitive to attempt to make the U.S. completely self-sufficient for all of its healthcare supply needs. Nevertheless, an important lesson of the COVID-19 pandemic is that the U.S. must certainly have more domestic manufacturing capacity of healthcare supplies to cope with disruptions of the normal supply chain. This requires developing a strategic blend of U.S. manufacturing capacity that can surge to meet pandemic-level demand, coupled with the established low-cost, high-volume infrastructure of near-sourced and global sources.

*The U.S. must have more domestic manufacturing capacity of healthcare supplies.*

**Ramping Up Quickly:** The logistics, space requirements, and expense of storing much more than 60 days of supplies in a reserve are considerable. The surge production capability that is available, either domestically or overseas, must be able to ramp up production rapidly during the buffer period offered by a reserve. By definition, surge capability involves surplus production capacity either in the form of well-maintained but underutilized production lines or facilities that can be easily and quickly converted to produce high-demand products.

**New Incentives For Surge Production:** The development of surge production capacity will require programs that make it economically feasible for manufacturers to invest in and maintain physical plant that will be optimized only in times of crisis. This would require an array of government funding, grants and incentives that could include financing the expansion of existing U.S. plants, purchasing additional production equipment and guaranteeing above-market production/source and raw materials to activate in a pandemic. In addition, capacity agreements between the Strategic National Stockpile and manufacturers can be the foundation for federal stockpiles, which would, in turn, create a higher level of production on a regular basis to support investment in additional production capacity.

**Supporting Sustainable Levels Of Production And Sourcing:** The strongest approach would be to procure and manage specified amounts of equipment while investing in manufacturing capacity (plants, machinery, raw materials) to ensure that these inventory levels can be continuously replenished during a pandemic. Planners should take into account both strategic and economic considerations when deciding where to invest and source products.

## Sustainable And Replenished Stockpiles

**The Disadvantages Of Static Stockpiles:** “Buy and hold” stockpile strategies, such as requiring providers to maintain 90 days’ worth of PPE inventory, risk falling short of the massive quantities of supplies required in a pandemic. These requirements are also logistically unworkable. For example, a 90-day supply of high priority products for of a moderately-sized community hospital of 350 beds would require the equivalent of 13-15 tractor trailers of space; there are more than 5,000 community hospitals in the U.S. In a future COVID-19-level event, any government stockpile needs to be replenished by a robust manufacturing/replenishment infrastructure.

*A 90-day supply of high-priority products for a 350-bed hospital would require 13-15 tractor trailers of space.*

**Creating Dynamic National Stockpiles:** In addition to the forward-deployed PPE and Critical Product Reserve, the federal government should continue to maintain and expand a select number of centralized stockpiles with the primary goal of supporting state and local government needs during a crisis and serving as a backstop to the commercial supply chain. Even under normal circumstances these stockpiles would be dynamic, with distributors assisting government managers in replenishing and managing products in order to make sure that inventory is up to date and properly handled. During a crisis, the stockpiles would then be replenished, as needed, by the surge manufacturing infrastructure. Stockpiles should include both finished goods and key raw materials to enable surge manufacturing.

## End-User Aligned Supply Chains

**Distribution Channels Need To Be Specified:** The surge-driven competition for products that drove up prices and encouraged profiteering brokers to enter the marketplace during the COVID-19 pandemic was the result, in part, of the entry of non-traditional customers, such as local governments, charities, retailers, restaurants, and grocery stores, into the traditional health industry supply chain. Government planners must strengthen communication and expectations between the Strategic National Stockpile, state agencies and local authorities, as well as with the commercial market. This can be accomplished through the establishment of specified distribution channels aligned by end user.

**Alignment By End User:** Aligning end users to a specified distribution channel establishes roles and expectations. It reduces confusion. It also allows for better forecasting of demand and allocations. In an emergency, end users should not have to rely on unfamiliar suppliers or processes to access supplies; they should have the ability to use the same source they use every day. Their primary suppliers need to be stocked to supply the first order received and replenished to satisfy future orders.

**The End User Matrix:** While the focus of HIDA is on its healthcare provider customers, the alignment of supply chains to end users would impact other types of consumers. Designing a pandemic response model in which each supply chain is clear will improve pre-pandemic planning as well as communications and logistics during a crisis. The matrix below provides an example of how supply chains could be classified according to end user type.

Supply Chains Defined By End User

End User		Designated Supply Channel
Healthcare Providers	>>	Medical Products Distributors
Medical Laboratories	>>	Medical/Lab Distributors Scientific Distributors Manufacturers
Public Sector Essential Workers	>>	Government Procurement Healthcare Distributors

Supply Chains Defined By End User, *continued*

End User		Designated Supply Channel
States, Counties, Cities	>>	Government Procurement/Stockpiles Federal Stockpile
Private Sector Essential Workers	>>	General Office Suppliers Industrial Suppliers Healthcare Distributors Retail Suppliers
General Public	>>	Retail and Online

## Putting The Framework Into Action: National Legislation Building On The PAHPAI Model

This framework is a public-private partnership that draws on the respective strengths of the federal government and the private sector.

On the public side, before a crisis, the government can set priorities regarding which products to stockpile and where to source them. It can provide the resources for “flex” reserves that can be drawn upon when a crisis suddenly drives up demand. On the private side, distributors are equipped to do what the government is not: handling the logistics of managing and delivering billions of units of PPE and supplies to 300,000 healthcare sites during a time of crisis.

Fortunately, there is already a model for deploying this type of partnership: the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAI).

### The PAHPAI Model

**Public-Private Partnership Under PAHPAI:** PAHPAI addresses all aspects of pandemic preparedness. It establishes a public-private partnership to assist the Assistant Secretary for Preparedness and Response (ASPR) in the Department of Health and Human Services in the development of various preparedness response programs. PAHPAI governs important national response infrastructure such as the Strategic National Stockpile and the Hospital Preparedness Program. It also establishes programs to help hospitals, healthcare facilities, and other public and private sector entities to increase medical surge capacity before, during, and after public health emergencies. In the beginning of 2020, HHS was in the initial stages of pursuing the mandates set out in PAHPAI when the COVID-19 pandemic struck. It was already taking advantage of a productive partnership with HIDA and its members through various work groups.

**The Importance Of Work Groups:** A key feature of the public-private partnership established in PAHPAI is the creation of work groups. Experts from public and private partners analyze current market volume, capacity, and viable product substitutions/alternatives for specific products. For example, the exchange of information in the work group on needles and syringes provided the Strategic National Stockpile additional insight that the types of needles needed for prevention (mass public health vaccination campaign), are also needed for treatment in hospitals as well as for everyday patient therapies, such as treating diabetes. As a result, HIDA’s secured, web-based Mapping Tool provides federal partners with commercial market information on medical distribution centers’ aggregated inventory levels of critical products such as needles and IV Solutions.

*Work groups bring together experts from public and private partners to analyze market volume, capacity, and viable substitute products.*

## New Legislation Building On The PAHPAI Model Needed

**A More Robust Partnership To Build A More Robust Supply Chain:** This framework would require a more comprehensive public-private partnership than is currently provided by PAHPAI. The establishment of a forward-deployed PPE and Critical Product Reserve, maintenance of dynamic national stockpiles and development of surge manufacturing capacity are interconnected issues that would require a commitment of resources and planning time over a multi-year horizon.

**The Role Of The Public-Private Partnership:** Using the work group model, an ongoing public-private partnership would assist the ASPR and the Strategic National Stockpile to identify 1) how much of which products to have in the distributor-managed reserve, 2) which products and quantities should be in Strategic National Stockpile and 3) how to work with manufacturers to develop additional capacity and production diversification. In addition to identifying specific products to be held in a pandemic response inventory, the work groups would analyze the market capacity for identified products, their impact on patient care, and the complexity involved in developing reserves of each product, such as the availability of raw materials, shelf life, manufacturing complexity and capacity, size of product and lead times.

**The Medical Supplies For Pandemics Act Of 2020:** H.R. 6531, the Medical Supplies for Pandemics Act of 2020, and its companion in the Senate, S. 3827, provide for the establishment of the public-private framework described in this paper. Both bills were introduced with bi-partisan sponsors and support and HIDA and its members are working for their passage.

## The Role Of HIDA

**Uniquely Positioned:** HIDA is uniquely positioned to assist in the public-private partnership from a data and insights perspective. HIDA represents 100 distribution companies operating 500 medical distribution centers across the country. Additionally, the HIDA Education Foundation has direct relationships with 130 manufacturers, group purchasing organizations, healthcare providers and other stakeholders. These companies make, source and contract for PPE including those that make PPE, testing supplies, diagnostics, infection prevention products such as hand sanitizer, respiratory treatment products as well as other key products needed to deliver vaccines and medical countermeasures.

**Experienced Partners:** HIDA members are established partners with ASPR and Strategic National Stockpile on pandemic initiatives providing subject matter expertise from our PPE Council and market-based councils to provide deeper insights into market dynamics in end-user segments such as hospitals, labs, physician offices and nursing homes. HIDA has a 20-year history of aggregating distributor sales data for use by industry partners. We also have a best-in-class healthcare informatics partner and deep knowledge of the products and markets. Our ability to ingest, aggregate and report insights from data that can inform ASPR and the managers of the Strategic National Stockpile is proven and unparalleled.

For further information about this report: [HIDA@hida.org](mailto:HIDA@hida.org)



310 Montgomery Street  
Alexandria, VA 22314



Leading Healthcare

### **Statement for the Record on the Medical Supply Chain and Pandemic Response Gaps During the COVID-19 Pandemic**

The Michigan Health & Hospital Association (MHA) represents all 134 Michigan acute care hospitals and several freestanding inpatient psychiatric hospitals. Many MHA members are healthcare systems encompassing other care settings such as nursing homes, hospices, and inpatient rehabilitation facilities. Every segment of Michigan's healthcare system has felt the impact of the COVID-19 pandemic. What was first a devastating surge of disease in Southeast Michigan in spring of 2020 shifted to a statewide impact in late fall and early winter. During March and April 2021, COVID-19 shifted its damage to adults below age 60 and even to a number of children as schools reopened. The assistance from the U.S. Congress through provider relief funds, and assistance to states and municipalities from the American Rescue Plan Act are deeply appreciated as MHA members continue to serve patients with COVID-19 and patients who have delayed physical and mental health care due to the pandemic.

When the COVID-19 pandemic hit Michigan in late March 2020, hospitals in Southeast Michigan immediately began experiencing shortages of supplies and equipment that were critical to the ability to provide patient care. Personal protective equipment (PPE) for hospital staff includes gloves, gowns, face shields, N-95 face masks, and goggles for eye protection.

Without proper equipment, healthcare workers, patients, and visitors were put at risk of virus exposure, and without proper medical supplies, it was impossible to treat patients effectively and safely. In response to the shortages, health systems across Michigan were forced to seek PPE from local businesses and manufacturers that had extra supplies, rely on health systems in other markets that were experiencing fewer COVID-19 cases, and in some cases even went to gray markets for critical supplies. Existing hospital supply chains had little experience with international markets. The MHA had the good fortune to partner with the procurement division within the State of Michigan Department of Technology, Management and Budget (DTMB). DTMB had existing access to agents and purchasing resources overseas, and in China, to vet production facilities, manufacturers, and suppliers offering PPE. Even with the state's purchasing power and reliability of its manufacturing sources, no PPE would be delivered for several weeks while the growth of Michigan's COVID-19 cases was increasing exponentially in April of 2021.

#### **Supply Reserves**

Prior to the pandemic, the healthcare supply chain had forced market prices lower which moved PPE production overseas. Years of progressively lower reimbursements for healthcare services allowed for little investment in stand-by capacity of supplies, equipment, pharmaceuticals, or space. Shortages were also exacerbated by an insufficient stock in the national stockpile and variation between states in stockpiles and emergency management supports, leaving many organizations to fend for themselves during the public health emergency to acquire critical supplies.

*Brian Peters, Chief Executive Officer*

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Michigan's initial assistance from the Strategic National Stockpile (SNS) was disappointing. Upon receipt of the first delivery from the SNS, Governor Whitmer contacted the MHA to inquire about the duration of time the delivery could support care in a Southeast Michigan hospital with a large and growing COVID-19 patient population. That first SNS delivery could not accommodate the personal protection equipment needs for an entire eight-hour shift.

Later in the initial surge, health facilities began receiving some direct shipments from the federal strategic national stockpile. These were more helpful, but also presented problems. Hospitals had little to no advance notice before receiving the shipments. In some cases, deliveries arrived at one facility and need to be routed to the appropriate facility or location with an ability to receive shipments. Advance knowledge of the receipt of these shipments likely would have changed decisions from purchasing to moving supplies between facilities. The state did not have knowledge of the details of federal allocations and consistently reached out to the MHA to try to determine what hospitals may or may not have received from the federal government.

Many health systems operate in multiple regions and/or states. Due to their size and economies of scale, healthcare systems can freely move supplies between their facilities and often locate supplies and materials in centralized warehouses of their own. Traditional methods of state and federal emergency assistance continue to look at each hospital as a distinct and independent location. The MHA believes this led to many shipments being sent inefficiently to a hospital location, which the health systems then redistributed between facilities, regions, and states. Coordinating emergency management within the context of health systems could reduce inefficiency and better position the government to respond to future emergencies.

#### **N-95 Masks**

The most serious shortage of protective equipment for staff was the lack of N-95 masks. The airborne nature of the COVID-19 coronavirus made the N-95 level of protection an absolute necessity for frontline staff in hospitals. This means physicians, nurses, environmental services workers, staff providing transport and food services; anyone in the hospital working with or near patients with infectious COVID-19. N-95 masks are usually discarded after every patient encounter to protect hospital staff and other patients from the spread of infectious disease. Because of the number of patients with COVID-19, their length of stay, and the unknowns about the infectiousness of COVID-19, N-95 mask supplies expected to last several months were exhausted within days. One small hospital thought it had a full year supply of N95s with 7,500. The hospital went through that stockpile during the first four weeks of the pandemic and was left scrambling for sourcing as the yearly use rate became the average monthly usage.

The state did not have the logistics in place to distribute federal shipments quickly and efficiently. In early April, a large health system in Southeast Michigan was critically short on N95 masks. The MHA received a call at 6:30am on Saturday that the facility would run out of PPE by 6:00pm on Sunday. While the state had just received a disbursement from the federal strategic national stockpile, they did not have the personnel to count and package the supplies to be shipped out to healthcare providers. This health system ended up sending several employees to the state warehouse that Saturday to help sort and ship the supplies, so the facility could avoid running out of masks that weekend.

In addition to the shortage, the price of N95s skyrocketed. Some health facilities reported paying \$12 per mask for N95s that cost less than \$1.00 just a few months previous.

**Paralytic Agents for Ventilated Patients**

Even more frightening than the shortage of N-95 masks was the shortage of drugs necessary for critically ill patients who needed ventilation. Patients using ventilators need paralytics to reduce the physiological stress of respiratory failure and improve the tolerance of invasive life support. Intubation rates of patients with COVID-19 patients was extremely high early on during the first surge as it was considered the primary course of treatment. Being ventilated requires a significant quantity of pharmaceutical paralytics to keep patients comfortable. Due to the shortage of PPE, hospitals were using extra-long tubing for IV administration. This allowed for pharmaceutical delivery from outside the room. This led to a tremendous volume of IV tubing being used, and in many cases pharmaceutical products being left behind in that tubing or not fully reaching the patient. The need for more paralytic agents and more drug per patient led to many hospital pharmacies running critically low on paralytic agents. Ordering additional supply was curtailed by pharmaceutical company limits. Hospital amounts were only allowed to increase by a certain percentage above the amount ordered in the previous month. A 15 percent increase in allocation was significantly inadequate as the patient population needing ventilation was triple the number (or more) from the month prior. Luckily, Michigan's hospitalization numbers began declining as the shortage of paralytics hit truly critical levels. To our knowledge every patient that was intubated had an appropriate dosage of pharmaceutical paralytics. Michigan came dangerously close to that shortage impacting patient care. Everyone working on the supply of these pharmaceuticals, inside and outside of the hospital, was deeply fearful of what would happen to our patients.

**Conclusion**

The COVID-19 coronavirus pandemic exposed the need for all sectors of the healthcare system to be nimble and flexible. We must cultivate the ability and opportunity to make decisions quickly, to easily collect data without increasing the workload on the hospital workforce doing patient care, to retool systems to accommodate a fast-growing patient population, and to move resources to produce necessary supplies.

Most important is creating and maintaining the overall ability in our public and private systems to make and accept change in regulation and policy during a long-term crisis. More than a year into the pandemic, state and federal response organizations have not made changes to acknowledge the hospital field is organized almost entirely into a series of systems, often located across state lines. Policies designed to preclude the potential misuse of prescription drugs prevented the allocation of pharmaceutical supplies to Michigan hospitals even when the caseload and death rates in Michigan were headline news.

Most emergency preparedness is related to single tragic occurrences which require a fast, short-term response. The COVID-19 pandemic required long-term thinking and multiple versions of response. The MHA encourages the members of the Committee to consider this fundamental circumstance as it works on legislation for future preparedness and response.

May 17, 2021



The Honorable Gary Peters  
 United States Senator  
 724 Hart Senate Office Building  
 Washington, D.C. 20510-2204

***Munson Healthcare Statement on The Medical Supply Chain and Pandemic Response Gaps Prepared for: U.S. Senate Committee on Homeland Security and Governmental Affairs***

Dear Senator Peters:

Munson Healthcare is the largest rural healthcare provider in Michigan, consisting of nine hospitals and related organizations, we serve 540,000 residents in 24 counties across 11,000 square miles of northern lower Michigan. We are proud of our response to the COVID-19 pandemic and specifically of our ability to source and network to obtain the needed supplies and equipment to ensure the highest quality of protection for our employees and care for our patients. However, our success was independent of any coordinated state or federal response.

Specifically, we saw a significant lack of communication, transparency and coordination between healthcare providers, the state and the federal government. For example, there were significant gaps in a coherent understanding of what makes up the "national stockpile" including a definitive list of supplies available including the basics of PPE and the more esoteric and variable items that ranged from enteral feeding supplies, solutions, extension tubing, vaccine and other treatments. This is an area where additional clarity and understanding would be important as we face future pandemics. Additionally, we would encourage efforts at the federal level to better manage stock rotations and expiration dates to ensure that we are not faced with a supply of expired supplies such as the large quantities of expired N95 respirator masks.

As a key partner in delivering care and protecting our community, we appreciate the Committee's focus on proactively addressing medical supply chain gaps so that we are all better prepared to confront the global pandemics of the future.

Should you have any questions, please feel free to contact me, or Mr. Gabe Schneider, Director of Government Relations for Munson Healthcare, who can be reached at [gschneider@mhc.net](mailto:gschneider@mhc.net) or 517-449-6453.

Sincerely,

A handwritten signature in black ink, appearing to read 'Edwin A. Ness'.

Edwin A. Ness, President & CEO  
 Munson Healthcare

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## Statement for the Record on COVID-19 Supply Shortages

At the beginning of the COVID-19 pandemic, the federal government and the states were unprepared to protect our critical workforce by providing necessary PPE and other material and equipment.

States relied on the Strategic National Stockpile (SNS) for the planned PPE and medical equipment and other supplies. The Demands of COVID vastly outstripped the SNS supply.

The Federal government left states to fend for themselves, with the President stating for "respirators, ventilators, all of the equipment—try getting it yourselves." This put states in a bidding war against each other within an already distorted market.

The supply chain relied on foreign manufacturers.

At significant cost and effort, the State of Colorado procured a risk-reducing supply of PPE, medical equipment, and assorted goods in response to the COVID-19 pandemic.

This material and equipment must be properly stored and managed to ensure that the State is prepared to meet critical needs during a crisis.

After a careful analysis of anticipated federal capacity, private sector supply chain resilience and a needs assessment to protect critical personnel in Colorado during a crisis, it was determined that Colorado, like other states, must anticipate a gap in the federal government and private sector's ability to provide PPE and medical supplies for an extended period of time during a pandemic.

As a result, Governor Polis directed the State to build, store, and maintain an emergency stockpile of critical PPE sufficient to bridge the gap and protect Coloradans.

Buying in a crisis exposed the state to potential fraud, low-quality products, non-delivery, price gouging. We minimized the impacts through strong controls, but other states weren't so lucky.

WSJ Article:

[A landmark White House move left states to secure medical equipment themselves, causing problems that still haven't abated](#)





**Statement for the Record**

**Submitted by**

**The Premier Inc. healthcare alliance**

***“COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps”***

**Senate Homeland Security Committee**

**May 19, 2021**

The Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the Senate Homeland Security Committee hearing titled “COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps,” scheduled for May 19, 2021. We applaud Chairman Peters, Ranking Member Portman and members of the Committee for holding this hearing to examine lessons learned from the COVID-19 pandemic and ways to strengthen the nation’s medical supply chain.

Premier Inc. is a leading healthcare improvement company and national supply chain leader, uniting an alliance of more than 4,100 U.S. hospitals and health systems and approximately 200,000 alternate site providers to transform healthcare. With integrated healthcare quality, cost and supply chain data and analytics, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier’s sophisticated technology systems contain robust data from nearly half of U.S. hospitals and 300,000 ambulatory clinicians. Premier is an agnostic, data-driven organization with a 360° view of the supply chain, working with more than 1,300 manufacturers to source the highest quality and most cost-effective products and services. Premier’s work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data-driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products.

**Premier’s Reflections & Learnings From COVID-19 Response Efforts**

From the beginning of the COVID-19 pandemic, Premier has been at the forefront of response efforts working around the clock to ensure hospitals, health systems, and alternate site providers across the country had access to the necessary PPE, medical supplies and pharmaceuticals to treat COVID-19 patients. Premier has spent significant time reflecting on the experience of the healthcare industry during COVID-19 response efforts to determine elements that worked well as well as areas for improvement for the future. Premier’s reflections have found that:

- Elements that Have Worked Well:
  - Nimbleness and ingenuity of the private sector to anticipate and identify needs as well as respond quickly to fill gaps
  - Formation of the Private Sector Supply Chain Coalition to provide a coordinated and collaborative response to the government and in the market
  - Sharing of supply chain data that accounted for both supply and demand from neutral, vendor agnostic, and value orientated entities
  - Regulatory flexibilities and waivers from FDA, CMS, HRSA, and CDC that were delivered rapidly

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- Timely and regular access to government leaders and openness to input
- Elements that Led to the Current Situation and Points of Failure.
  - In spite of efforts by Premier and others to counter the trend, a focus for the past 20+ years to move manufacturing offshore as a means to reduce costs to offset decreasing healthcare reimbursement. This is because emerging economies:
    - Are more willing to take greater environmental regulatory risks
    - Have large populations of low-cost labor
    - Have incentives to move manufacturing to their markets
  - Lack of centralized upstream visibility into supply chain to determine source of raw materials and finished goods. This resulted in a lack of understanding of vulnerabilities, foreign reliance on manufacturing, and impact as export bans and manufacturing shutdowns were announced.
  - Unprecedented demand both globally and nationally that led to an imbalance in the supply vs demand, e.g., 17X increase in surge demand for N95 masks.
  - Export bans and manufacturing shutdowns globally.
  - Insufficient supplies in the Strategic National Stockpile (SNS) and cumbersome process for accessing supplies in the stockpile.
  - More reactive approach vs a proactive approach by the government at the outset. Product was not allocated to the "hot spots" because there was not clear identification of them until late.
  - Fragmented approach to securing supply (private sector vs federal vs states) led to increase in prices as multiple entities competed for the same inventory and out-bid one another.
  - Lack of clear visibility of distributor fulfillment lead to uncertainty on where products were delivered. This continued uncertainty left providers with dwindling confidence in the normal supply chain and proliferated more maverick and forward buying, as well as hoarding. This also led to a rampant gray market and many entities purchasing counterfeit products.
  - Insufficient national strategy and plan for addressing global pandemics, including confusion regarding which federal agency was responsible.
  - Existence of patent restrictions that impeded access to ancillary products needed for care such as viral swabs.

#### **Strengthening the Healthcare Supply Chain to Address Future Pandemics**

To strengthen the supply chain to address future global pandemics, Premier has robust recommendations on how the existing private sector supply chain can be further enabled and augmented. Premier's guiding principles include:

- Augment the existing private sector supply chain to better respond to global pandemics through diversification and transparency. The private sector supply chain is highly functioning and should be further enabled, not disrupted.
- Develop a cohesive and holistic national strategy for addressing global pandemics and stabilizing the U.S. supply chain to respond to surge demand for critical medical supplies and drugs.
- Identify critical medical supplies and drugs needed to treat a global pandemic and associated comorbidities. This identification should occur via a public-private advisory council that includes representatives from manufacturers, GPOs, distributors, physicians, pharmacists, laboratorians, and others. This list must be dynamic and regularly updated as technology advances, best practices are identified, and the practice of medicine evolves.

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- Create upstream visibility into the supply chain to understand sources of raw materials and manufacturing facilities. This information is critical to assess vulnerabilities and prioritize what critical medical supplies and drugs should be focused on initially to assure adequate diversification of the supply chain.
- Develop a nimble, automated supply chain data infrastructure so that there is a real-time mechanism to track supplies and predict shortages.
- Advance payment and delivery system reforms that hold providers accountable for the health of a population, budgets and transparent outcomes. This will incent improving the health of a population, which will both improve patients' comorbidities and attention to care management to sick patients. Acting within a budget helps reduce long-term financial pressure from rising healthcare costs.
- Leverage technology to implement comprehensive infection prevention and antimicrobial stewardship programs in nursing homes to provide meaningful assistance with infection control.
- Design stockpiles to create coordination rather than competition between state, local and national stockpiles.
- Leverage supply and demand data from GPOs, who serve as neutral, vendor-agnostic, and value- orientated entities to drive transparency in the supply chain and forecast demand needs.

#### **Incentivizing Domestic Manufacturing**

Regarding domestic manufacturing, there are five major barriers that policy proposals must address. These barriers include: 1) capacity; 2) environmental regulations; 3) labor costs; 4) availability of raw materials; and 5) historical policy decisions that advantaged offshoring.

While Premier recognizes a need to incentivize domestic manufacturing, we also recognize a need to ensure global diversity in manufacturing. For example, moving all manufacturing onshore would create a similar overreliance on a single geographical region. Therefore, Premier recommends that there be at least three global suppliers of the final form, ancillary products and raw materials for critical medical supplies and drugs. Global suppliers should be from geographically diverse regions including at least one domestic supplier.

To stimulate domestic manufacturing, Premier has thought critically about how to incentivize manufacturers to invest in domestic manufacturing while also ensuring that domestically manufactured goods are price competitive with globally sourced products. To that end, Premier recommends a two-part approach that leverages tax credits as a mechanism for achieving these goals.

#### Part I:

- A 30% tax incentive for investments to support the domestic manufacturing of critical medical supplies and drugs, including their raw materials. Examples of how the tax incentive could be applied (not intended to be all inclusive – examples only):
  - Investments in advanced manufacturing equipment or machinery
  - Investments to repurpose existing abandoned facilities
  - Investments to build new facilities
  - Investments to expand existing facilities
  - Investments to relocate foreign facilities back to the U.S.
  - Investments to upgrade facilities to meet EPA requirements
  - Regulatory filing fees for new domestic entrants to the market (e.g. FDA, NIOSH, etc.)

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- The tax incentive should be reevaluated in five years to determine its ongoing necessity and whether the incentive level can be lowered or eliminated.

Part II:

- A 10% tax credit on the income generated from the sale of domestically manufactured goods. This would also help lower the cost of goods manufactured domestically and make them price competitive with globally sourced products.
- To be prudent, companies found to be price gouging or selling counterfeit products by the Department of Justice, Federal Trade Commission, or other agency should not be eligible for the tax credit. Guardrails would help ensure companies aren't artificially increasing their prices to take advantage of the tax credit from higher sales prices and support the integrity of the supply chain.

To truly create a long-term domestic manufacturing infrastructure that is sustainable, incentives for onshoring manufacturing must be coupled to committed purchasing volumes so new entrants to the market have a guaranteed sales channel. To accomplish this goal while cultivating global diversity, Premier recommends that government purchasers be required to contract for critical medical supplies and pharmaceuticals from a mixture of onshore, near-shore (such as Central and South American countries) and off-shore countries. Purchase thresholds based upon a geographical region can help prioritize domestic manufacturers while ensuring global diversity and sustainability of the supply chain.

Finally, Premier recommends that Congress and the Administration consider incentives for healthcare providers to purchase domestic manufactured critical medical supplies and drugs through programs such as tax incentives, CMS bonus payments, etc. to create committed purchasing volume for domestic suppliers and offset higher acquisition costs.

**Developing a Real-Time Inventory Data Management System**

A major barrier during the pandemic was the lack of downstream visibility into the exact quantities of critical medical supplies and drugs that were on US soil at any given time. As a result, there was a surplus of products in many parts of the nation while communities in the New York City area were operating in crisis mode and leveraging household products such as garbage bags to protect frontline workers. Moreover, because of the lack of understanding of what product availability risks existed, there was excessive purchasing of products, the emergence of unscrupulous and fraudulent vendors, and hoarding which created shortages for others.

In response to the urgent need to understand product availability and risks, the federal government stood up a health information collection process to determine these factors across the supply chain. However, this system was antiquated and created substantial additional work for healthcare providers, with hospitals being asked to report inventory on hand via Excel files. Hospitals and other providers were also being asked to report to state and local officials with similar, and sometimes different, data which created redundancies and further confusion. Furthermore, the system proved to be of little use as inconsistent data nomenclature meant hospitals were reporting "boxes" and "units" differently from one another, and in many cases, many hospitals opted to cease reporting inventory levels due to the administrative burden and fear that available products would be confiscated by the government.

A key component to an end-to-end supply chain solution is an on-call, nimble automated data collection infrastructure that the nation can call upon in any future crises similar in magnitude to COVID-19. Rather

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than standing up an inadequate and duplicative system as we experienced during the pandemic, the nation needs a system that can track critical product availability - from the raw materials, to manufacturer, to distribution, to state and national stockpiles, to hospital inventory. This system would exist behind the scenes and be ready to be "turned on" in a moment's notice. It would provide visibility of supplies in hospital inventories with detailed information that would enable accurate and intelligent decisions about supply allocation and needs at the local, state, regional and national levels. This information would inform dynamic and appropriate product allocation and distribution strategies, minimize hoarding, and enable powerful and accurate prediction, enabling the nation to manage supplies during the crisis. Moreover, this data could be made available to providers in a metropolitan statistical area to help them understand community risks and enable intelligent purchasing.

This data infrastructure would also strengthen the SNS by:

- Creating visibility into inventory via a standardized data nomenclature and automated acquisition of data across the SNS, manufacturers, distributors, and within healthcare systems that is tied to real-time resource demand data.
- Providing inventory monitoring and advanced alerts of critical supply inventory levels warranting movement of product from the SNS to points of care, ramping up production of certain supplies, etc.

To accomplish these goals, policy changes are needed to provide data rights to create predictive algorithms and to acquire and utilize data for surveillance. In addition, rules must be established to provide assurances that government will not seize inventory and to ensure confidentiality around supplies held by different competitors. To encourage reporting, the policy might require that providers report the data as a condition of eligibility for receiving supplies from the SNS during pandemics.

#### **Strengthening the Strategic National Stockpile**

Regarding the Strategic National Stockpile (SNS), Premier strongly supports the vision of the Administration to augment the SNS to better respond to global pandemics by enabling public-private partnerships. However, to develop a truly cohesive and holistic national strategy for addressing future global pandemics and stabilizing the U.S. supply chain to respond to surge demand for essential medical supplies and drugs, Premier believes that it is critical to take a slightly broader approach to creating a true end-to-end supply chain solution that is transparent, diverse, and reliable. In addition, it is critical to not only focus on the quantity on hand for critical supplies, but also focus on the time to inventory and ensuring the U.S. has contractual relationships established, including contingency and redundancy plans, to ramp up production expeditiously and efficiently upon identification of need.

The SNS is the supply chain of last resort for health systems, alternate site providers, and first responders. Therefore, the SNS must be built by providers for providers. The SNS must also leverage analytics and insights to assist providers in the delivery of care during global pandemics that is in the best interest of patients and ensure access to the right supplies at the right time.

Premier's vision for the next generation SNS includes the following elements that can be accomplished via a public-private partnership:

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- Establish a Public-Private Advisory Council - The SNS should establish a Public-Private Advisory Council that includes representatives from the private sector such as manufacturers, group purchasing organizations, distributors, physicians, pharmacists, nurses, laboratorians, non-acute providers, patients, professional associations, and others as well as representatives from the public sector such as federal agencies (HHS, FEMA, ASPR, CDC, CMS, FDA, SAMHSA, the Veterans Health Administration, Indian Health Services, etc.), prisons, first responders, state and local representatives, and others. The advisory council should leverage a multi-committee structure to ensure the appropriate expertise is represented for specific product categories such as pharmacy, lab, nursing homes, pediatrics, etc. The advisory council will be critical to ensuring the SNS is soliciting feedback from a broad range of entities to augment its operations through a data-driven approach, remain unbiased and vendor agnostic, support a collaborative decision-making process, identify innovative products, and continuously refine the vision of the SNS. Essentially, the advisory council structure helps ensure the SNS is built by providers for providers.
- Identify A List of Critical Medical Supplies, Drugs & Other Supplies Necessary to Manage a Surge - The Public-Private Advisory Council should be tasked with:
  - Identifying the list of critical medical supplies, drugs, medical foods, and other supplies needed to treat a global pandemic and associated comorbidities that should be included in the SNS, including determining the most cost-effective product where multiple options may exist within a single product category or therapeutic category; and
  - Annually, at minimum, assessing, refining, and revising the list of critical medical supplies, drugs, medical foods, and other supplies contained in the SNS to account for product discontinuations, emerging technologies, changes in clinical guidelines, and identification of best practices.
- Create Transparent & Diverse Sourcing for Critical Medical Supplies & Drugs - Establishing a transparent, diverse, and reliable supply chain is essential for ensuring the U.S. is prepared to respond to future global pandemics. This is critical information to understand vulnerabilities, foreign reliance on manufacturing, and impact of geopolitical issues such as export bans and manufacturing shutdowns. A robust sourcing strategy for the SNS should:
  - Create transparency by obtaining upstream visibility into the supply chain to determine source of raw materials, ancillary products, and finished goods. All manufacturers contracted with the SNS should commit to providing upstream visibility into the sourcing for their products to provide a holistic view.
  - Assure diversity by ensuring there are several suppliers of raw materials, ancillary products, and finished goods from geographically diverse regions.
  - Leverage multiple sourcing options including contracting directly with manufacturers, contracting with group purchasing organizations to help aggregate purchasing volume and keep prices competitive, and recruiting and incentivizing the entry of new manufacturers for product categories that lack diversification. Policy changes may be needed to 1) permit the SNS to pursue innovative contracting methodologies to meet the vision of the next generation SNS; and 2) amend the Federal Supply Schedule to incentivize domestic manufacturing and ensure a stable supply at a sustainable price.
  - Identify and contract with at least a primary and secondary manufacturer for each critical medical supply and drug. The contract should stipulate the ability of the manufacturer to meet certain supply requirements within a specified period during surge demand,

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redundancy and contingency plans for manufacturing, requirements for safety stock and warehousing of the product, and quality standards that must be ensured.

- The Public-Private Advisory Council should be tasked with:
  - Developing criteria for awarding SNS contracts to manufacturers;
  - Vetting and approving all SNS contracts to manufacturers to provide an agnostic and unbiased voting process;
  - Providing recommendations for warehousing at the product level; and
  - Prioritizing product categories for domestic manufacturing.
- Develop a Network of Stockpiles Throughout the Country - Stockpiles should be designed to create coordination, rather than competition. Stockpiles should also be curated to meet specific needs such as acute, alternate site, first responders, etc. as each segment of healthcare will have varying needs. Therefore, the SNS should develop a network of stockpiles that creates a hub-and-spoke model with the SNS as an anchor that offers a full array of services that is complemented by state and local stockpiles to optimize supply. To further optimize the availability of supplies as close to the point of care as possible, the SNS should explore opportunities to leverage health system and alternate site provider warehouses in major metropolitan areas or in rural areas. Finally, to ensure the network of stockpiles are interoperable and complementary to one another, the Public-Private Advisory Council should be tasked with developing national standards that all stockpiles must meet at minimum.
- Rotate Inventory - The SNS should rotate soon-to-expire product out of the SNS. This can be accomplished either by 1) contracting with manufacturers to rotate inventory; or 2) selling short-dated products to health systems and alternate site providers at a discounted rate. The second option would allow the SNS to recoup some expenses associated with managing the SNS and reinvest those dollars while also assisting healthcare providers with decreasing their acquisition costs. Any sale of covered outpatient drugs from the SNS should be exempted from Medicaid Best Price calculations. Rotation of inventory should also occur as products are discontinued or removed from the SNS.
- Create an Efficient & Dynamic Fulfillment Process - The current process for accessing the SNS is cumbersome and state specific. Therefore, the SNS should create a single, streamlined, and efficient electronic process for making requests of the SNS along with a standardized process for responding to requests. It is also critical for the SNS to develop a dynamic distribution methodology that leverages a data-driven approach to ensure products are available in the right place at the right time. Finally, a nimble and flexible distribution method is also needed to move supplies amongst health systems from areas with excess product or declining need to hot spots or areas with increasing needs.
- Test the Functionality, Readiness & Reliability of the SNS - To ensure the next generation SNS can deliver during future global pandemics, it is critical to periodically pressure test the system. Annually, without prior notice, the SNS should require all contracted manufacturers to provide the SNS with a specified quantity of product. An annual test allows the SNS to ensure all contracted manufacturers can expeditiously and efficiently ramp up production to meet surge demand, as well as ensure production lines remain operational and are maintained.
- Analyze & Report - Transparency regarding the efficiency and utilization of the SNS is critical to understanding its purpose and continued need. The SNS should be transparent regarding

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distribution of supplies and drugs from the SNS and therefore should provide, at minimum, a detailed monthly report of what supplies were requested versus distributed to where and in what quantities. During a public health emergency, reporting should occur weekly.

**Conclusion**

In closing, Premier appreciates the opportunity to submit a statement for the record on the Senate Homeland Security Committee hearing focusing on the gaps in the medical supply chain and nation's response to the COVID-19 pandemic. Premier looks forward to working with Congress and other stakeholders to develop a cohesive and holistic national strategy for addressing global pandemics and stabilizing the U.S. supply chain to respond to surge demand for critical medical supplies and drugs.

If you have any questions regarding our comments or need more information, please contact Soumi Saha, PharmD, JD, Vice President of Advocacy, at [soumi\\_saha@premierinc.com](mailto:soumi_saha@premierinc.com) or 732-266-5472.

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STATEMENT  
OF

ROBERT J. WIEHE, SENIOR VICE PRESIDENT, CHIEF SUPPLY CHAIN AND  
LOGISTICS OFFICER

UC HEALTH  
CINCINNATI, OHIO

BEFORE THE

COMMITTEE ON HOMELAND SECURITY  
AND GOVERNMENTAL AFFAIRS

COVID-19 PART II  
EVALUATING THE MEDICAL SUPPLY CHAIN AND PANDEMIC RESPONSE

MAY 19, 2021

Thank you to the committee for the opportunity to provide a statement on the medical supply chain and pandemic performance gaps

As the Senior Vice President, Chief Supply Chain and Logistics Officer for UC Health, my responsibilities include strategy and oversight for sourcing, acquiring and distributing all supplies and capital equipment within our health system. UC Health is an integrated healthcare system serving the Southwest Ohio and Northern Kentucky region, and one of 125 Academic Medical Systems in the country. In partnership with the University of Cincinnati, UC Health combines clinical expertise and compassion with research and teaching – a combination that provides patients with options for even the most complex situations.

The challenges that have emerged from the COVID-19 pandemic are unlike anything we have encountered in our lifetimes. The healthcare sector has been one of the hardest hit by this pandemic. Coronavirus-related disruptions to supply chains, combined with dramatic increases in global demand, are among one of the many challenges that hospitals and systems faced over the last year.

#### **Current State – May 2021**

- Stabilization stage for hospital supply chain but future remains unpredictable
- Hospital Supply Chains are determining their “new normal.” We are still very much operating under the pretense that the pandemic is not over.
- Need for high daily demand of PPE has lessened but sourcing of preferred PPE remains constrained.
- Supply distribution partners has begun to reduce allocation over the last 2-4 months with “some” categories – all categories affected but slight reductions currently.
- Reduced requests for PPE from surrounding care facilities related to nursing homes.
- Key product pipelines remained strained:
  - Chemo rated nitrile exam gloves – may be long-term disruption due to foreign source of manufacturers.
  - Certain cleaning agents and disinfectants
  - “Sterile surgeon gowns” supply is improving but the pipeline is guarded.
- Efforts are underway to work with suppliers, GPOs to identify supplies most at risk for shortage and developing working plans to strengthen resources and pipelines to these products.
- Sourcing Strategies now include diversifying suppliers to secure multiple sources for future needs

***Regional and Strategic National Stockpile Assistance***

Starting in February 2020, the Ohio Department of Health (ODH) surveyed hospitals in order to ascertain our PPE levels and to prepare for statewide stockpile resource allocation.

In partnership with the ODH, the Ohio Hospital Association and the Regional Healthcare Coordinators, we monitored ongoing PPE needs and inventories in order to inform distribution allocations. Additionally, this network of communication allowed for sharing of guidelines and recommendations for PPE conservation, and regional and state cache limitations due to expired or destroyed supplies. Hospitals were asked to utilize the limited regional and state cache prior to the Strategic National Stockpile (SNS) as they continued to distribute PPE from our regional cache to healthcare providers, EMS, law enforcement and hospitals through EMA request processes.

In early March 2020, UC Health received our first supplies from our regional cache and in late March we received our first shipment of PPE from SNS. We continued to receive shipments of supplies in the months of April and May.

Timing and detailed communication is an area of opportunity for any future distribution from stockpiles.

**Opportunities for Improvement**

I would like to go on record that the cooperation I have witnessed both internally and externally to UC Health has been in a word - remarkable. This includes but is not limited to government officials, healthcare leaders, and industry leaders from the non-healthcare sector, physicians, nursing, and supply chain. Supply chain disruptions continue to be more frequent as geopolitical events, weather events, and other outside forces continue to impact all industries. If we can continue to have an open dialogue and learn from our collective experiences and other industries, we will be in a much better position when the next supply disruption happens.

Specific to the healthcare industry, I would offer the following specific examples of areas that can continue to be strengthened and improved. Most of these have not changed from my prior statement during the height of the pandemic:

1. Communication and transparency along the entire supply chain must be improved. Genuine transparency from demand forecasting to supply and raw material availability is crucial and builds trust along the supply network. Improved data capabilities and infrastructure should be adopted across the healthcare supply chain to help facilitate these efforts. Systems still do not have assurances from preferred distributors/vendors of supply availability.

2. Create a more diverse and possibly regionalized approach for critical supplies. Supply chain resiliency should be favored over low cost for critical supply items.
3. Require manufacturers of critical supplies to report raw materials and manufacturing capacities to the government to provide insight into the most important supply chains. This would be similar to how pharmaceutical manufacturers are required to report to the government.
4. Require health systems or hospitals to carry a minimum day on hand supply of critical supplies. This would be similar to the CMS requirement for facilities to maintain enough fuel, potable water, etc. to operate for a minimum of 96 hrs. My suggestion would be to mandate a minimum of 30 days inventory on critical PPE for all health systems. I do believe most systems are carrying more supplies today due to supply chain frailty.
5. Improve transparency and communication on the national stockpile. This would include details on the supplies and quantities that are being stockpiled and how these will be allocated during a time of need.
6. Build a larger national stockpile of critical supplies. This would eliminate the competition for supplies when and if a crisis strikes again. We should avoid scenarios where government and industry are trying to secure the same resources and competing against one another.
7. Improve domestic capabilities and capacities for the manufacturing of critical raw materials and supplies. On February 26, US Health and Human Services (HHS) Secretary Alex Azar told the House Appropriations Committee that the country had a stockpile of 12 million N95 masks, but according to HHS estimates, it needs 300 million to cover an emergency. The estimated annual production capacity in the US and Mexico is 65 million masks.
8. Provide economic incentives for manufacturers to improve domestic manufacturing capabilities.

### **Conclusion**

Thank you for the opportunity to share my insights on this very important subject. COVID-19 has provided yet another example of the vulnerability of critical healthcare supply networks and the need to look for new creative solutions to overcome these disruptions. I believe we have already learned many valuable lessons that can be used to improve our healthcare supply chain resiliency and ultimately improve outcomes during future supply disruptions. I look forward to working with the Committee and others to offer my thoughts and help to strengthen our healthcare supply chain from end to end and create greater transparency and resiliency in the process.



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providing quality, compassionate care to everyone, every time

May 17, 2021

The Honorable Gary Peters  
Chairman, Committee on Homeland Security & Governmental Affairs  
United States Senate  
Washington, D.C. 20510

Dear Chairman Peters:

On behalf of Sparrow Health System, I respectfully submit comments to the Committee regarding the topic "Evaluating the Medical Supply Chain and Pandemic Response Gaps."

Headquartered in Lansing, Sparrow Health System is mid-Michigan's premier healthcare organization and the region's largest private employer. Providing quality care to tens of thousands of people each year, Sparrow has over 115 sites of care, including a Level 1 Trauma Center in Lansing, Sparrow Clinton Hospital in St. Johns, Sparrow Ionia Hospital in Ionia, Sparrow Carson City Hospital in Carson City, and Sparrow Eaton in Charlotte.

Throughout the pandemic Sparrow has discharged over 2,550 COVID positive inpatients, performed over 497,000 COVID-19 tests, and administered over 122,800 COVID-19 vaccines.

Sparrow has experienced inflated medical supply costs due to manufacturer's inability to hold their prices and fill hospital orders. For example, we experienced a 500% increase in exam glove prices with limited supply options in the market. The increasing levels of manufacturer backorders, compounded with short notice, caused disruptions to hospitals forcing us to source from secondary non-contracted vendors that typically result in higher pricing.

Except for vaccines, Sparrow received minimal medical supplies from government agencies during the pandemic. Nearly all supplies and equipment were acquired by Sparrow via the open market. In several situations, the open market presented inconsistent supply availability, increased delivery lead times, and inflated pricing, typically well above pre-pandemic price points.

At one point during the pandemic Sparrow had only four days' supply of masks. Faced with increased demand and extremely short supply we had to be innovative, so we participated in the Battelle mask reprocessing project through their center located in Detroit. Over 15,000 N95 masks were reprocessed and are currently held in our stockpile.

The coordination from the Federal Strategic National Stockpile and allocation to states, then to regions, and ultimately to hospitals and healthcare providers had limited impact and often, no advanced knowledge what inventory was available or the timeline of availability. When supplies did become available, we were well beyond the initial surge, and had effectively sourced our own stockpile. While we worked hard to meet our supply needs, partners in our region like

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long-term care facilities, nursing homes, and homes for the aged were not as successful and sought assistance from Sparrow and we proudly assisted with their supply needs.

We appreciate the Committee's work to boost domestic manufacturing of personal protective equipment.

Sincerely,

A handwritten signature in black ink that reads "John A. Shaski".

John A. Shaski  
Government Relations Officer

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May 17, 2021

The Honorable Gary Peters  
Chairman  
Committee on Homeland Security & Governmental Affairs  
U.S. Senate  
Washington, DC 20510

The Honorable Rob Portman  
Ranking Member  
Committee on Homeland Security & Governmental Affairs  
U.S. Senate  
Washington, DC 20510

Dear Chairman Peters and Ranking Member Portman:

Trinity Health appreciates this opportunity to submit a statement for the record for the Committee on Homeland Security & Governmental Affairs hearing entitled *COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps*.

In support of our Mission, Trinity Health is answering the call to serve our communities in their greatest time of need due to COVID-19. As one of the nation's largest non-profit health care organizations serving communities across 22 states, Trinity Health recognized the need for a coordinated national approach. Our facilities have worked together to prepare for and respond to the pandemic and its spread across the United States.

Trinity Health has rapidly responded to the challenges facing our health system due to COVID-19. Even in the absence of a coordinated federal response, Trinity Health acted swiftly. In February 2020, we activated our System Incident Command which allowed us to quickly react and streamline decision making and effective use of resources. Trinity Health's response has involved innovative approaches across our system including utilizing our Fort Wayne, Indiana distribution center (DISC) to rapidly allocate and distribute personal protective equipment (PPE), medications, equipment and more to our facilities across the country.

The COVID-19 pandemic has highlighted inadequacies in the health care supply chain. There is a global reliance on China for both raw materials and finished goods. Approximately 80 percent of active pharmaceutical ingredients (API) originate in China. Countries all around the world are going to China at the same time for the same goods, creating competition and security risks. In the United States, the lack of coordination and transparency in the governmental response has acutely appeared in the supply chain that has been charged with bringing life-saving medicines, supplies and PPE to hospitals and other providers.

The lack of coordination is coupled with the reality that the federal government became a new competitor for these same products. While well-intentioned, the efforts of the Federal Emergency Management Agency (FEMA) to build the Strategic National Stockpile (SNS) as well as attempts by legislators to help acquire supplies, has ultimately resulted in competition with hospitals for the same products. Additionally, suppliers have not been transparent with hospitals and other providers regarding product capacity, demand and allocation. Trinity Health has many examples when supplies were delayed or canceled. In one instance, we were informed that a contracted shipment of COVID-19 test kits would be reduced by 65 percent and the Department of Health and Human Services redirected the shipment to a different state. Ultimately, these competing variables have resulted in a supply chain that is inefficient and inadequate to meet the demands of a pandemic.

Trinity Health is pleased that the American Rescue Plan included provisions to address the persistent supply concerns highlighted above by investing in the Disaster Relief Fund and incenting domestic manufacturing. We are encouraged that President Biden's American Jobs Plan includes policies to bolster the SNS and onshore active pharmaceutical ingredients. Congress should secure the health care supply chain through measures to:

- Develop transparent SNS policies that include information on the inventory, product specification, location, quality and accessibility of the stockpile and ensure this information is accessible to health systems; replenish and keep SNS stock fresh; and establish a cadence of disaster drills with health systems where product is shipped, consumed by the health system and replenished in the SNS.
- Develop a process to track the status of critical product shortages and require supply chain disclosure (location of raw materials, distribution channels) for medical product approvals informed by the precedent set for the COVID-19 vaccine emergency use authorization approval process.
- Establish a coordinated national supply chain through a public-private partnership that includes a "marketplace" for supplies with information on demand. This effort should be led by supply chain experts with government at the table.
- Provide additional tax incentives to expand domestic manufacturing of supplies.
- Provide incentives to increase the availability of reverse-transcriptase polymerase chain reaction (RT-PCR) testing material.

Trinity Health stands ready to help inform your response to the COVID-19 pandemic. We have subject matter experts who are available to provide supply chain insights based on our experience. Please contact Tina Grant, Senior Vice President of Public Policy and Advocacy, at [grantw@trinity-health.org](mailto:grantw@trinity-health.org) or 517-643-0784 for additional information.

Sincerely,



Michael A. Slubowski, FACHE, FACMPE  
President and Chief Executive Officer  
Trinity Health

**Statement of the U.S. Pharmacopeia**

**Submitted to the Senate Homeland Security and Governmental Affairs  
Committee**

**For the Hearing on "COVID-19 Part II: Evaluating the Medical Supply Chain and  
Pandemic Response Gaps"**

May 19, 2021

The United States Pharmacopeia (USP) is pleased to submit the following statement for the record on the hearing "COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps."

USP is an independent, scientific, global non-profit organization founded in 1820 and dedicated to building trust where it matters most: in the world's medicines, dietary supplements, and foods through rigorous science and public quality standards.<sup>1</sup> A core pillar of USP's mission is to help strengthen the global supply chain so that the medicines people rely on for their health are available when needed and work as expected. The Federal Food, Drug, and Cosmetics Act of 1938 created the statutory requirement that medicines sold in the United States generally must adhere to USP's public quality standards to help ensure the quality of medicines and the safety of patients. USP works closely with the Food and Drug Administration (FDA), other US government agencies, and across the health and science communities to develop USP standards, which are enforced by FDA. USP is governed by more than 500 organizations, including scientific, healthcare practitioner, consumer, and industry communities, as well as dozens of government agencies, who together comprise the USP Convention.<sup>2</sup>

The global medical supply chain is a complex marketplace of manufacturers, suppliers, and distributors from many countries. When a breakdown in the supply of medical products such as personal protective equipment or critical medicines occurs, patients and national security are at risk. The global pandemic caused by COVID-19 has resulted in calls to strengthen the resiliency of the supply chain and ensure that the supply of equipment and medicines is not interrupted. USP is actively supporting these efforts by leveraging our scientific capabilities and global reach.

Building a more resilient medicines supply chain will require a multi-faceted approach that is focused on:

1. **Identifying upstream supply chain risks to avoid disruptions.** USP has developed informatics capability that helps identify risks in the upstream supply chain to enable better avoidance of downstream impact on patients

<sup>1</sup> USP standards are developed by Expert Committees and Panels comprised of more than 750 scientific experts. These experts collaborate to develop USP standards through an open, transparent process, offering the ability to adjust standards to confront public health emergencies, adapt to new industry practices, and keep up with evolving science and technology.

<sup>2</sup> USP's other governing bodies include its Board of Trustees and Council of Experts.

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- and provides information needed to help mitigate supply chain risks with investments, policy reforms or other actions.
2. **Fostering additional capacity for critical medicines.** USP supports building strategic resilience into the supply chain through public-private partnerships and by incentivizing adoption of innovations that can bolster supply such as the deployment of advanced pharmaceutical manufacturing technologies.
  3. **Preserving the supply of antimicrobials.** USP is committed to building and maintaining the supply of antimicrobial medicines, both here in the US and globally. USP is helping to ensure antimicrobial medicine quality around the world, in an effort to reduce the proliferation of poor-quality medicines.

### **Identifying Risks in the Upstream Pharmaceutical Supply Chain**

USP urges Congress to prioritize the identification of upstream supply chain risks, which can enable regulator and industry action to reduce the frequency and duration of drug shortages while also providing evidence to inform public investment and policy reforms that build more resilience. USP believes that such an approach should include elements to predict and prevent shortages before they occur rather than focusing on responding to drug shortages.

It is well documented that quality issues remain a primary contributor to drug and medical product shortages.<sup>3,4,5</sup> These quality concerns are most often concentrated in the upstream supply chain, which refers to the drug manufacturing process where raw chemicals, key starting materials, active pharmaceutical ingredients (APIs), and finished dosage forms (FDs) are produced, refined, packaged, tested, and labeled. The lack of real-time information (that is consistently updated) about the upstream supply chain fosters uncertainty to whether a single disruption can have serious negative consequences to patients downstream.<sup>6</sup>

Neither a single government agency nor any industry entities have a complete view of upstream supply. This lack of clarity can lead to a poor understanding of the risks that may be inherent in the United States medicines supply.<sup>7</sup> For these reasons, there is growing consensus on the need to identify, characterize, and quantify risks in the upstream supply chain – in a way that unleashes the information required to draw meaningful conclusions – through approaches that are sensitive to the implications of unnecessary exposure of the data, which has the potential to move markets or cause unnecessary panic.<sup>8</sup> Leveraging sensitive data for standard-setting purposes, but maintaining its confidentiality, has been fundamental to USP's work for 200 years.

<sup>3</sup> Pew Charitable Trusts. 2017. *Drug Shortages*. Available at: [https://www.pewtrusts.org/-/media/assets/2017/01/drug\\_shortages.pdf](https://www.pewtrusts.org/-/media/assets/2017/01/drug_shortages.pdf).

<sup>4</sup> International Pharmaceutical Federation (FIP). 2013. Report of the International Summit on Medicines Shortage. Available at: [https://www.fip.org/files/fip/publications/FIP\\_Summit\\_on\\_Medicines\\_Shortage.pdf](https://www.fip.org/files/fip/publications/FIP_Summit_on_Medicines_Shortage.pdf).

<sup>5</sup> FDA. 2019. *Drug Shortages: Root Causes and Potential Solutions*. Available at: <https://www.fda.gov/media/131130/download>.

<sup>6</sup> USP. 2020. *Increasing Transparency in the Medicine Supply Chain*. Available at: <https://www.usp.org/sites/default/files/usp/document/about/public-policy/increasing-transparency-medicine-supply-chain.pdf>.

<sup>7</sup> USP. 2021. *Are My Medicines at Risk of a Shortage?* Available at: <https://qualitymatters.usp.org/are-my-medicines-risk-shortage>

<sup>8</sup> Healthcare Leadership Council-Duke Margolis Center for Health Policy. 2021. *100 Leading Healthcare Organizations Release Disaster Preparedness Recommendations*. See at page 3, "There was a general consensus that more visibility is needed into the supply chain – both upstream and downstream, which includes informing key stakeholders about usage, levels, and dispositions, while maintaining protection of confidential commercial information and protecting any information that is sensitive from a national security perspective." Available at: [https://www.hlc.org/wp-content/uploads/2021/01/disaster\\_preparedness\\_report-FINAL.pdf](https://www.hlc.org/wp-content/uploads/2021/01/disaster_preparedness_report-FINAL.pdf).



### **Mapping the Supply of Medicines**

USP is generating insights through the USP Medicine Supply Map, which helps identify, characterize, and quantify risk and resilience in the upstream medicines supply chain. The Medicine Supply Map uses multiple sources of information to identify the sites of raw ingredient and medicine manufacturing. This data is enriched with information about risk drivers like price, ingredients, and FDFs, and covers 92% of US-approved generic prescription drugs. The model is also informed by insights on the use of USP quality standards in nearly 22,000 drug, API, and excipient manufacturing sites in 150 countries.

Using this information, USP has built a model to predict and assess the resiliency of drug products based on the expected resiliency of their upstream supply chains. These insights can be leveraged as part of a proactive effort to identify medicines that require investment or policy action to help ensure their supply. At a very practical level, these insights can help inform tabletop exercises to determine what medicines to prioritize, understand which drug supply chains to “stress test,” or to track the impact of these efforts.

To help build a more sustainable supply chain, USP recommends that Congress support efforts to identify and assess the resiliency of drugs and medical products.

### **Fostering Additional Capacity for Critical Medicines**

A recent report from the National Academy of Sciences highlighted that “there is a strong consensus that advanced pharmaceutical manufacturing technologies can and must play a central role in creating an agile, flexible industry that can produce high-quality drugs reliably,” but notes the implementation of advanced manufacturing technologies (AMT) will require the partnership and sustained investment of all stakeholders to move the capabilities forward.<sup>9</sup> Pharmaceutical continuous manufacturing (PCM) is one of the most promising AMT advancements because it enables continuous use of a production line which can yield significantly more product output and thereby enhance supply and resilience. This type of AMT has the potential to improve manufacturing efficiency, reduce production costs, and significantly reduce environmental footprints.

In traditional batch manufacturing, the raw materials that are eventually transformed into the final product (e.g., a pill) are blended, weighed, compressed, and coated in different machines, in different locations, at different times. This requires many starts and stops in the manufacturing process. As the name suggests, under PCM the final product can be produced from start to finish in one location and in one continuous process. While there are numerous advantages to PCM, such as real-time monitoring (to ensure quality without slowing production), a lower degree of human error with automation, and potentially lower costs, there are also significant challenges that stand in the way of broader adoption of PCM, including the following:

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<sup>9</sup> National Academy of Sciences. 2021. *Innovations in Pharmaceutical Manufacturing on the Horizon: Technical Challenges, Regulatory Issues, and Recommendations*. Available at: <https://www.nap.edu/catalog/26009/innovations-in-pharmaceutical-manufacturing-on-the-horizon-technical-challenges-regulatory>.



- PCM technology requires upfront investment in new infrastructure, research, and development, while existing market dynamics make realizing a positive return on investment uncertain, especially for low margin generic medicines.
- Limited experience with PCM across regulators, and limited guidance for industry, leads to uncertainty among manufacturers seeking regulatory approval for products manufactured with PCM technology.
- Manufacturers may not have access to staff who are trained with the technical knowledge of the processes, capabilities, and constraints of PCM to enable them to develop new process analytical technologies and statistical tools while also hiring or retraining their workforce.

USP believes challenges to broader adoption of PCM can be reduced through policy reforms that offer a mixture of incentives for manufacturers while bolstering public-private partnerships. Solutions in these areas can help support one of the five priorities of the Strategic National Stockpile (SNS) 2.0 initiative to expand domestic manufacturing and help reduce vulnerabilities in the medical supply chain.<sup>10</sup>

The development of public standards for medicines produced with PCM technology will accelerate adoption and help ensure product quality. The establishment of public quality standards represents the core of USP's work. These standards articulate key attributes of a quality medicine including identity, strength, and purity specifications of drug products and ingredients. Importantly, USP public quality standards also provide industry and stakeholders with scientifically validated guidance that can accelerate scale-up and provide greater regulatory predictability. USP is exploring new forms of standards to spur broader adoption of PCM and to help foster quality assurance that could help create a more resilient supply chain.

#### **Preserving the Supply of Antimicrobials**

The lack of a resilient supply of antimicrobials is a profound threat to both global health and US health security. The upstream supply for these products is riddled with risk and the clinical effectiveness of these medicines is diminishing rapidly as a result of antimicrobial resistance (AMR). AMR is defined as the ability of a microorganism (for example, bacteria, viruses, and some parasites) to stop an antimicrobial (such as antibiotics, antivirals, and antimalarials) from working against it. AMR has been identified by the World Health Organization (WHO) as the next public health crisis; without action, AMR is estimated to cause 10 million deaths per year by 2050.<sup>11</sup> In the United States, the Centers for Disease Control and Prevention estimates that nearly 3 million Americans acquire infections resistant to antibiotics each year, resulting in about 35,000 deaths.<sup>12</sup>

<sup>10</sup> HHS. *Building a More Resilient Strategic National Stockpile*. Available at: <https://www.phe.gov/about/sns/Pages/sns-next-generation.aspx>

<sup>11</sup> World Health Organization (WHO). 2020. *Urgent health challenges for the next decade*. Available at: <https://www.who.int/news-room/photo-story/photo-story-detail/urgent-health-challenges-for-the-next-decade>

<sup>12</sup> Centers for Disease Control and Prevention. 2019. *Antibiotic resistance threats in the United States*. Available at: <https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ant-threats-report-508.pdf>



Resistance is driven mostly by overuse, inappropriate prescribing, and the proliferation of poor-quality versions of these medicines.<sup>13,14</sup> Among the leading supply chain risks for antimicrobials is the concentration of API manufacturing in China and finished drug manufacturing in India along with the continuing exit of manufacturers of these medicines due to multiple factors including the often-short lifecycles of antimicrobials as a result of pathogen resistance and generally extremely low rates of reimbursement.

Unfortunately, existing efforts to address AMR have been diverted due to the ongoing pandemic, during which misuse of antibiotics to treat COVID-19 has increased; in many circumstances, patients are receiving antibiotics for COVID-19 although they are entirely ineffective in treating it. For instance, a meta-analysis found that 71.9 percent of patients hospitalized with COVID-19 before mid-April 2020 received antibiotics, even though only 6.9 percent of these hospital admissions were associated with bacterial infections.<sup>15</sup> A similar study by Pew Charitable Trusts suggests that in 96 percent of admissions for patients diagnosed with COVID-19, an antibiotic was given prior to confirmation of a bacterial infection.<sup>16</sup>

USP supports a multifaceted approach to addressing AMR, including the prioritization of building resiliency for the supply of antimicrobials, building capabilities among global stakeholders to reduce the proliferation of poor-quality medicines, address over prescribing and inappropriate prescribing, improved adherence to treatment regimens, and implementing steps to fund or incentivize more research and development into next generation products.<sup>17</sup>

In addition, through the USP Quality Institute, we have been leading the way on research into the link between AMR and substandard medicines. Substandard medicines are an underrecognized driver of AMR and result when products are poorly manufactured or degrade due to improper storage, thereby rendering these medicines ineffective for treating illnesses and infections. We have seen that AMR emerges not only when a pathogen is exposed to substandard antimicrobials but can also spread within a product class. As a consequence of pathogen resistance, new antibiotics may not always treat infections effectively.<sup>18</sup> As a result, it is critical to preserve the quality of the existing supply of antimicrobials as well as protect the supply of any new drugs.

Addressing the threat of AMR will require political will and global cooperation to strengthen regulatory systems and secure the medicines supply chain. We urge Congress to prioritize efforts to prevent AMR from becoming the next global public health crisis.

<sup>13</sup> PLoS One. 2021. *In vitro* growth competition experiments that suggest consequences of the substandard artemisinin epidemic that may be accelerating drug resistance in *P. falciparum* malaria. Available at: <https://doi.org/10.1371/journal.pone.0248957>

<sup>14</sup> Nature Scientific Reports. 2020. Development and selection of low-level multi-drug resistance over an extended range of sub-inhibitory ciprofloxacin concentrations in *Escherichia coli*. Available at: <https://doi.org/10.1038/s41598-020-65602-z>

<sup>15</sup> European Society of Clinical Microbiology. 2020. Bacterial co-infection and secondary infection in patients with COVID-19: a living rapid review and meta-analysis. Available at: [https://www.clinicalmicrobiologyandinfection.com/action/showPdf?pii=S1198-7433\(20\)29209-29304-7](https://www.clinicalmicrobiologyandinfection.com/action/showPdf?pii=S1198-7433(20)29209-29304-7)

<sup>16</sup> Pew Charitable Trusts. 2021. *Could Efforts to Fight the Coronavirus Lead to Overuse of Antibiotics?* Available at: <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2021/03/could-efforts-to-fight-the-coronavirus-lead-to-overuse-of-antibiotics>

<sup>17</sup> USP. 2020. *Addressing Antimicrobial Resistance*. Available at: <https://www.usp.org/sites/default/files/usp/document/about/public-policy/policy-position-paper-amr-2020.pdf>

<sup>18</sup> Nature. 2020. Development and selection of low-level multi-drug resistance over an extended range of sub-inhibitory ciprofloxacin concentrations in *Escherichia coli*. Available at: <https://www.nature.com/articles/s41598-020-65602-z>



**Conclusion**

USP applauds the Committee for holding this important hearing. USP looks forward to providing information and expertise and will work with Congress and stakeholders to advance our shared goal of helping to ensure the resiliency of the medicine supply for American patients.





**Questions for the Record**

Responses from

**Dr. Shereef Elnahal**

President & CEO

COVID-19 Part II:

Evaluating the Medical Supply Chain and Pandemic Response  
Gaps

United States Senate

Homeland Security &

Governmental Affairs Committee

July 9, 2021

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Post-Hearing Questions for the Record  
Submitted to Shereef Elnahal, M.D.  
From Chairman Gary C. Peters

COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps  
Wednesday, May 19, 2021

1. **What impact did the federal government's actions have on the swift and equitable distribution of needed medical supplies to States and hospitals across the country?**

As I mentioned during my testimony, University Hospital benefited from the national stockpile of supplies -- including N-95 masks, gowns, ventilators and more -- with the support of our state government. I do believe that we were only able to benefit from the stockpile due to advocacy, support, and intervention from Governor Philip D. Murphy and the New Jersey Department of Health. We also benefited significantly from the CARES Act, which provided funds that kept our hospital afloat during the worst of the pandemic. Without the CARES Act money, we projected that we would have found ourselves unable to make payroll by August of 2020. And, without access to supplies from the national stockpile, University Hospital would have struggled in ways similar to the experiences of hospitals just across the Hudson River, where some staff found themselves using trash bags as isolation gowns, and other ad hoc PPE, to provide patient care.

2. **The Department of Homeland Security has designated 16 critical infrastructure sectors, one of which is Healthcare and Public Health, yet hospitals faced severe capacity and staffing challenges throughout the pandemic. How can the federal government improve critical health infrastructure throughout the country and increase resilience for future emergencies?**

There is still much work to do. The Biden administration is maximizing the use of the authorities under the Defense Production Act, which has had a beneficial impact and has led to real changes for vaccine accessibility and other supplies. One of the first Executive Orders President Biden signed after taking office dealt directly with the nation's supply chain, calling for a public health supply chain

resilience plan. As for the matter of financial solvency for institutions like University Hospital during times of crisis like this, we need meaningful, value-based payment reform to this effect, sooner rather than later. To continue depending on herculean, federal rescue efforts during these crises would indicate a failure to prepare.

There also needs to be significant investment in health care workforce resiliency and training, and the public health commissioned corps needs to be supplemented with an enlisted corps, or medical reserve, of health care professionals across the country who can be deployed domestically for public health emergencies. We relied on the incredible heroism of US Army Reserve clinicians, who were only available to us because our state government advocated for University Hospital to receive that assistance. These heroes are typically deployed abroad for their missions, and so investing in a domestic public health reserve corps would better prepare the entire health system for the next pandemic.

**3. How would you assess the support, transparency, and communication states received from the federal government – from the procurement and allocation of critical medical supplies to assistance increasing hospital capacity?**

COVID-19 exposed our nation's decades long struggle to maintain the strategic national stockpile of essential supplies and medication. This has been a long-term oversight that has spanned many decades. The national stockpile could have been equipped with more up-to-date, better equipment, especially ventilators. We also found ourselves competing with other hospitals and health care providers within and among states, due in part to the insufficiency of the national stockpile. There is little question that reform is needed. University Hospital supports strategies such as those at the core of the *Help Onshore Manufacturing Efficiencies for Drugs and Devices Act* and the *Pharmaceutical Accountability, Responsibility, and Transparency Act*. If these types of measures had been enacted prior to the pandemic, University Hospital would have been better positioned to meet the care needs of our community during a difficult time. And I believe they would help the country make great strides in building a more reliable, domestic-based supply chain for future health emergencies.

Regarding assistance with creating hospital capacity, the federal government was very helpful on that front. Under the leadership of the NJ Department of Health, we collaborated with the National Guard, Army Corps of Engineers, and other

federal heroes in uniform to stand up and run the field medical station in Secaucus, NJ, an essential resource for the Northern region of the state that allowed for hospitals to transfer convalescing patients and make room for new admissions. We also collaborated with the Army corps to establish an inpatient unit at a local, partner hospital that could be a more permanent resource for surge capacity in future pandemics.

However, these efforts were also ultimately ad hoc, and it was clear that we did not have a national pandemic surge strategy on which we could rely to guide efforts. This would be a worthy endeavor for the federal government to lead.

**Post-Hearing Questions for the Record  
Submitted to Shereef Elnahal, M.D.  
From Senator Jon Ossoff**

**COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps  
Wednesday, May 19, 2021**

**Please submit for the record an itemized list of the medical equipment, products, precursors for production of key medical supplies and products, and the pharmaceutical products that may swiftly be in high demand and of which we may have shortages across a range of plausible public health crises so that this committee can refer to such list as we consider other supply chains that may require reinforcement.**

In consultation with our Supply Chain Department at University Hospital, here is a list of supplies that would be in demand in **any** pandemic.

**Personal Protective Equipment**

- Nitrile Gloves
- Level 2 or higher isolation gowns
- Bouffant Caps
- N95 masks
- Powered Air Purifying Respirators (PAPR)
- Shoe covers
- Procedure masks
- Face shields/goggles/safety glasses

**Disinfectant**

- Hand Disinfectants
- Equipment disinfectants

**Ancillary items**

- Qualitative & Quantitative fit test kits
- Body bags
- Hospital Beds for surge space

Depending on the nature of the disease, ventilators and ventilator filters may also be needed and would be in short supply.

As for pharmacy supplies, here is a list of the classes/medications that were frequently considered by our staff at University Hospital during the pandemic for critically ill patients. Of note, most of this list could be generalized to all critically ill patients, which would cover pandemics not only related to respiratory pathogens, but also pathogens that cause gastrointestinal disease, hemorrhagic syndromes, and sepsis, all of which have life-threatening.

We have also included all medication regimens in the event of a pandemic surge, not just 'first line' therapies.

#### **Supplies:**

- Infusion pumps and channels

#### **Medications:**

- **COVID 19 (anecdotal increase in use during the pandemic - not treatments)**
  - Steroids: dexamethasone, hydrocortisone
  - Heparin/LMWH
  - Alteplase (ischemic strokes, massive PE)
  - Insulin (DKA)
- **Rapid Sequence Intubation/Neuromuscular Blocking Agents**
  - Etomidate
  - Succinylcholine
  - Rocuronium
  - Cisatracurium
  - Vecuronium
- **Pain Management**
  - Acetaminophen
  - Fentanyl (IV and patch)
  - Hydromorphone
  - Morphine
  - Ketamine
  - Methadone
- **Sedation**
  - Midazolam

- Lorazepam
- Diazepam
- Phenobarbital
- Propofol
- Dexmedetomidine

- **Vasopressors**

- Dopamine
- Epinephrine
- Norepinephrine
- Phenylephrine
- Vasopressin

- **Antidotes (not COVID specific)**

- Andexanet alfa
- Acetylcysteine
- Atropine
- Calcium gluconate/calcium chloride
- Calcium EDTA
- Crotalidate
- Cyproheptadine
- Dimercaprol
- Dantrolene
- Deferoxamine
- Digoxin immune fab
- Fomepizole
- Flumazenil
- Glucagon
- Hydroxocobalamin
- Leucovorin
- Levocarnitine
- Lipid emulsion
- Methylene blue
- Naloxone
- Octreotide
- Potassium iodide
- Physostigmine
- Pralidoxime
- Protamine
- Pyridoxine

- Sodium bicarbonate
- Succimer
- Thiamine

Simply put, a repeat of the COVID-19 pandemic would mean that all antimicrobials and antivirals could be in heavy demand. In the case of another COVID-19 surge COVID-19 vaccines, COVID-19 specific immunomodulators, and every other pharmaceutical listed on the attached NIH list of COVID-19 treatment options would be at risk.

**Post-Hearing Questions for the Record  
Submitted to Robert B. Handfield, PhD  
From Chairman Gary C. Peters**

**COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps  
Wednesday, May 19, 2021**

1. Based on your experience as a consultant for the Joint Acquisition Task Force, did the Trump Administration have a viable plan for the swift and equitable distribution of critical medical supplies? How would you assess federal interagency coordination and communication in procuring and distributing needed medical supplies?

**Problems Observed during the COVID19 Pandemic**

Disaster and emergency events in the United States have typically been regional and limited in duration; examples include hurricanes, floods, fires, earth-quakes, industrial accidents, or terrorist attacks. In all such cases, the event requires immediate follow-up on the part of state agencies but is not an on-going event beyond one or two weeks. The response to such disasters typically involves moving in supplies to surrounding regions, often following an established procedure for procuring and distributing readily available supplies (e.g., food, shelter, water, and relief goods). Supplies in these types of disasters are generally readily available. There is no problem in identifying qualified local suppliers for quick orders and shipping to impacted sites. The sourcing task is largely operational, and the primary task involves how to mobilize supplies to meet a time-sensitive demand quickly.

In 2020, the pandemic differed from regional disasters in a fundamental and significant characteristic. The shortage of critical PPEs (e.g., N95 masks, nitrile gloves) was global in nature, and the emergency continued to rage month after month. During COVID-19, both sourcing activities and supplies emerged as the weakest link in the disaster relief operations. COVID-19 was an epic disaster on a national and global scale, which impacted every state in the union. State agencies were unable to reach out for assistance from other states (who were equally overwhelmed), and challenges existed in getting support federal response agencies, which were equally disabled in their response.

How and why did this occur, and what can we learn from the events that transpired in 2020?

**The Need for a New Federal Responsive Shared Services Approach**

To address this question, it would be useful to step back and view the essential nature of the Federal government agencies and what they provide. Over the years, the Federal government has developed agencies with deep expertise to provide services to the public, which are also geared to be able to respond to any number of different emergencies that arise, whether they are healthcare-related, weather-related, terrorist events, etc. These agencies are themselves embedded in a vast network of other agencies (intergovernmental, nonprofit, for profit organizations) that also have expertise and provide services important to the public. In an important sense, each agency can be envisioned as a supply chain, that

delivers expertise and services to the public. In this context, the research question that arises is as follows:

Can/should the Federal government create a mechanism to coordinate (orchestrate) these largely autonomous supply chains, in a shared services context, to address the large scale problems that arise (such as COVID) which require a “whole-of-government” approach?

In effect, the pandemic response provides a case example that can be studied (in a post-mortem fashion) to develop and work through a new whole-of-government shared services problem-solving model, focusing on supply chain resiliency that can be mapped to four levels of maturity (outlined in this paper). By reviewing what happened during the pandemic we can learn from the practical problems that arose.

This situation is markedly different from what other supply chain initiatives are already doing (through multiple bills on Capitol Hill across many agencies), in that we are uniquely concerned with the whole-of-government coordination that becomes necessary when problems are national and global in scope. We need a blueprint for how government agencies can more effectively break down siloes, and come together during critical emergencies and respond as a united government effort.

Supply Chain Responsiveness requires that multiple agencies join forces “to transparently share information on shortages and share supplies of critical goods.” These networks share information both vertically with their own suppliers and distributors and horizontally through reciprocal information sharing with competitors. Development of the criteria for responsiveness will be captured, and established into a maturity model that identifies what the pathway for a federal national response center would look like, which would be folded into the paper.

I am planning a workshop being held with IBM to “unpack” the meaning of what is required to establish national supply chain responsiveness, and how such national capabilities could be leveraged as shared services in the future serving the interests of multiple Federal, state, local government and nonprofit and for-profit entities in a variety of emergency scenarios. We propose to have participants discuss the following criteria for establishing a new national response system for future emergencies. For each criteria, we propose to use the following framework (Figure 1)

**Current State:** What is the current state of this capability?

**Future State:** What would an ideal future state capability look like, and what are the attributes?

**Critical Success Factors:** What would be the enabling elements required to establish and put in this capability? What is the timeframe for development? Who should lead the initiative?

Figure 1 - Shared Services Framework

	Current State	Future State	Critical Success Factors
Global Independence			
Persistent and Agile			

Transparency and Traceability			
Flexibility			
Equitable Distribution			
Delivers effective cross-government shared services			

**Criteria:**

- **Global Independence**, government policies that can establish a system of acquisition and supply for areas which are critical to national security, which may include development of a domestic network of trusted suppliers who are willing and capable to be part of the response system fabric. This would entail development of a prioritization of critical supplies that are required for national security – and for each one, a policy for either development of a domestic capability, or a means for managing the supply of these items from global sources.
- **Persistent and Agility: Market Intelligence**: A primary requirement is the ability to monitor events globally, and establish early warning signals that may indicate a potential threat on the horizon. Today, much of the intelligence in this area is spread out across multiple agencies, including the Intelligence Community, the FBI, the State Department, and the DoD. There is a need for a more integrated team that can pull on all of these resources, to highlight potential threats that may impact national security. In the case of the pandemic, early warning of the COVID virus spreading was evidence in December and January, but this knowledge was not able to be translated into actions that led to preparation of the tidal wave that flooded our nation. Improved responsiveness requires agile networks that can quickly bring critical agencies into discussion where missions intersect. Interpretation of signals also needs to be translated into potential scenarios also needs to apply within and among agencies at Federal, state and local levels; but intergovernmental barriers are often formidable. Thus, a critical element will be to a) develop a central responsibility for tracking global events that may impact the country, b) translation of these risks into portfolio of materials required to response, and c) development of forecasts to estimate the total amount of materials required to response to the predicted risks. These decisions will need to be made by a cross-agency team, that may include BARDA, DHHS, CDC, DHS, FEMA, and the State Department. This should be developed as a council that can meet regularly to review updated MI reports.
- **Transparency and Traceability**: Access to material levels in the supply chain will become critical, through real-time visibility to inventory levels. Rather than keeping a single stockpile of material, the government should employ a virtual warehouse framework, to locate material in different facilities, perhaps within the Veteran Affairs and DOD Healthcare hospital systems. Visibility can be created through a Supply Chain Control Tower, which represents a virtual dashboard of critical material that is available to the government across multiple locations. This dashboard is a critical enabler, i.e., a dashboard of data, key business metrics and events across the supply chain that enables organizations to fully understand, prioritize and resolve critical issues in real time. A control tower requires a strong focus on data hygiene with continuous quality improvement through analytics technologies, blockchain, artificial intelligence, multi-cloud environments, etc. Inventory turns can thus be managed, as material that is close to being expired can be released and sold to the healthcare system in question, and replenished on a timely basis.

- *Flexibility*, or agility in response, refers to the ability to withstand different demand requirements that arise on short notice. 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. Flexibility also implies integrated teams with multiple agencies, expertise, and perspectives enabled by global monitoring to catch problems early and share responses. This capability will require a team of experts that can be developed quickly to respond to an emergency or crisis. The governance of this team needs to be established a priori, such that a central figure (perhaps the ASPR) leads the team, and calls on experts from each of the agencies to quickly develop insights and recommendations based on the data. The composition of this ad hoc team may vary based on the type of emergency (e.g. pandemic, terrorist threat, cyberterrorism, energy crisis, etc.) and may span any number of different agencies.
- *Equitable Distribution*: 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.
- *Delivery of Effective Shared Services*. To what extent could new national capabilities be leveraged by multiple Federal, state or local government entities as a shared service capable of responding to a variety of emergency response scenarios? This capability is required to ensure that the right level of expertise is being leveraged across agencies, to bring a coordinated and intelligent response that builds on the strengths, knowledge, and network of experts that can work together in a unified forum to solve a problem.

I believe an analysis is needed to identify the gaps between the current and future state in each of the areas shown in Figure 1. Specifically, I am proposing to lead a workshop, in which a group of experts will be first informed on the current state, and then opine on what they believe a recommended future state would look like, that would have enabled an effective, responsive, federal supply chain. The group will also brainstorm ideas on what the potential barriers may lie ahead, and the critical success factors required to overcome these barriers. This will produce a set of practical and actionable recommendations for government to close the gaps that exist today, and to move towards a more responsive federal supply chain as a desired future state.

In addition, new organizational models may be necessary to support new shared services and supply chain model to effectively leverage state, local and industry capabilities (e.g., Amazon, UPS, Federal Express, etc.) in a unified national response capability. A robust and well-integrated planning and governance framework will be needed to align and coordinate these interests throughout the life cycle of emergency response activities. Addressing data challenges will require a strong top-down mandate to drive cross-agency and inter-governmental data

standards and integration. The cultural shift will be necessary to tackle these issues on a whole of government basis will be a fundamental, make-or-break challenge. This set of recommendations may indeed require a completely novel shared services model, that will be set forth in a report produced as an outcome of this workshop.

2. In July 2019, the Acting Deputy Assistant Director for Health Care Operations of the Defense Health Agency, Christopher Priest, testified about the risks posed by relying on foreign sources for critical medical supplies. He warned that if China decided to cut off U.S. supply it would, “have a debilitating effect on U.S. domestic production and could result in severe shortages of pharmaceuticals for both domestic and military uses.” What steps should have been taken to protect the U.S. against this type of threat and how can the U.S. increase medical supply chain resilience?

As stated in my [earlier report for the IBM Business of Government \(Handfield, 2011\)](#) the U.S. medical system has been increasingly reliant on low cost manufacturing from overseas sources, a trend that has been occurring for the last thirty years. Much of this activity has been driven by the continued pressure of the healthcare system to buy pharmaceutical products and medical supplies at the lowest cost. Medical supplies include many of the items shown in Table 1 below, which includes surgical and N95 masks, gowns, latex gloves, catheters, single use tubing, Propofol, IV fluids bioreactor bags, and many other items. All of the products shown in Table 1 experienced significant supply shortages during the COVID crisis. Beginning as early as the 1970s many companies moved their manufacturing to low-cost regions to gain improved labor cost—often one of the highest contributors to the cost of goods sold. Offshoring was enabled by international trade agreements struck between nation states, reductions in duties and taxes and other government incentives. The offshoring of production often meant that firms established large, centralized, production facilities to exploit volume advantages, in locations such as China and India. Final products were manufactured in centralized facilities and then shipped around the globe to large distribution centers in the US and Europe. Many of the distributors of these products, including companies like Cardinal, McKesson, Owens and Minor, Premier, MedAssets, and others, bought them in large quantities at discounts, and then sold them in bulk to hospitals, based on contracts that promoted a “stack ‘em higher, buy ‘em cheaper” mentality. This practice was also encouraged by increased pressure on hospitals by CMS and private insurance companies to reduce patient costs. For products like nitrile gloves, there emerged near monopolies like Top Glove and Viet Glove in Vietnam.

For N95 masks, more than half of the world’s supply came from China, and in fact, much of that was produced in the Wuhan region where COVID originated! 3M also secured all of their raw materials for masks from China, and their factory there was directed to sell only within China by the government through April 2020.

In pharmaceuticals, as more common products became generic, many of the inputs for drugs, known as Active Pharmaceutical Ingredients were sourced from India, which then sources many

of their materials from China. Manufacturing is outsourced to Contract Manufacturing Organizations (CMO's) who are often evaluated based on a per unit price basis, and directed by brand pharmaceuticals to produce according to the "recipe" provided them using the suppliers they were directed to buy from.

There were inherent risks with buying low cost medical supplies and pharmaceuticals from Asia. First, there was a lack of direct control and oversight over operations, and the risk of GMP and quality problems was significantly higher. Second, most shipments were made by ocean freight, and the leadtimes for such shipments became longer and longer, as the ships became larger and slower and made more frequent stops (again to save money and drive down the cost of transportation). Distributors in the US tried to keep inventory as low as possible, and tried to keep as little safety stock on hand as possible. Domestic manufacturers of medical products could not compete with these low costs, and many went under or transferred operations to Asia. The Chinese tariffs created further problems as supply became constrained. One of the biggest risks overlooked was the remote possibility that export controls or product shortages would cut off our supplies of medical supplies, a risk which in fact came to fruition in early 2020. Another risk I observed during my work with hospital supply chains is that they often had very poor inventory management practices, with little visibility to their current inventory levels, which we referred to in our paper "[Blurry Vision: Supply Chain Visibility for PPE during COVID](#)".

#### **An Appeal to Congress and the FDA: Act now, before U.S.-made PPE all but disappears**

In my recent [testimony](#) to the US Senate [Sub Committee on Homeland Security and Government Affairs](#) on May 19 (COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps), I emphasized the critical need for developing independence from global sourcing of healthcare products from China. I also emphasized in [a Harvard Business Review article](#) the dependency of the Strategic National Stockpile on foreign sources of personal protective equipment (PPE), the bulk of which came from China. This hearing was in support of two bills by the Senate, one of which is advocating development of local domestic sources for critical healthcare supplies.

In response to the pandemic and the resulting PPE crisis, many domestic manufacturers sprang into action. New entrants came into the market, working hard to fill the PPE gap. Many existing manufacturers extensively retooled production lines to produce N95 masks. They have gone through the process of having these masks approved by NIOSH, and the majority have been certified. These manufacturers are now seeing a massive drop in sales as they are [faced with a glut of Chinese masks](#) that are cutting them out of the business.

This has left many of them struggling to survive, with idled factories and workers receiving pink slips. As a board member of the non-profit Project N95, we have had numerous discussions with domestic mask manufacturers who have told us that they likely have 30 days or 60 days left, before they are unable to continue and must declare bankruptcy.

Have we learned anything from this pandemic? The data we have is clear. As shown in our analysis of Twitter data (below), the number of times that “PPE shortages” came up escalated in the March and April 2020 timeframe, and did not recede until December 2020. Industry responded to the call, establishing domestic production facilities capable of producing billions of certified N95 masks. Yet now our government seems unable to commit to supporting these domestic mask manufacturers.

The major pipeline for distribution of masks to hospitals is through the “Big Three” distributors: McKesson, Cardinal Health, and Amerisource Bergen. These distributors have told domestic manufacturers that their prices are not competitive – despite the fact that these same distributors were not able to supply the United States during COVID, as they were not able to get access to Chinese-made masks. Even in the recent Presidential speech to Congress, members of Congress were seen on television, wearing Chinese-made KN-95 masks, which have the “folded ear straps” design, many of which have not been NIOSH certified. (see below).

Unless we all act fast, and unless the Feds do more than just introduce U.S. startups to McKesson & Cardinal Health (who won't stock these domestic suppliers at their current price-points) then these companies will all go belly-up.

Why is this happening? There are many factors at play, including issues around price. We would argue that value - particularly for pandemic contingency materials like PPE - is defined as affordable, reasonable, accessible and safe. The current approach our government is using only addresses short term affordability, It does nothing to ensure our ability to deliver accessible, safe materials in the future.

By letting small domestic manufacturers fall by the wayside we are potentially choosing to destabilize domestic healthcare and end-consumer supply of these critical masks for future pandemics or healthcare emergencies. The “future” may not be too distant, as more variants lead to localized shutdowns in the southern hemisphere. Letting domestic mask makers shutter their doors and go bankrupt this summer will only leave us more exposed by the fall as the risk of additional waves increases, as schools return to in-person instruction with only a portion of their populations vaccinated.

It's now that we have to consider the total cost of a supply chain strategy. Chinese goods may carry the lowest selling price when there is unlimited access to stock, but this low cost strategy can lead to complete supply chain impotence when faced with [barriers to access](#) as was seen during the early months of COVID in the US.

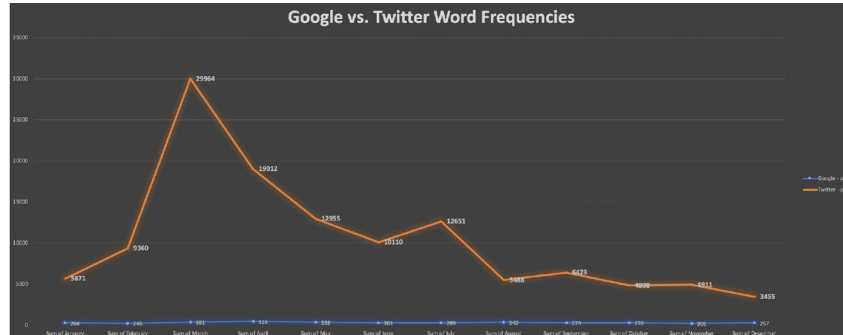
It is clear that the federal government is doing the bare minimum to create sustainable PPE supply - recent changes to [their mask mandate](#) failed to motivate anyone and the CDC only very recently updated guidance to allow health care facilities to return to conventional protocols -- meaning one use of a single-use N95.

The situation is similar for domestic manufacturers of rapid COVID-19 tests. While there was strong support for the research programs to create new tests, there is very little messaging on the importance of continued testing given the rise of variants. All of this has now left the domestic market quite stranded.

In light of the CDC messaging failures, the added failure of the federal government to properly prop up domestic mask manufacturers, and the hesitation to encourage disciplined testing with a concerted national message, there is an urgent need to act. What is needed?

- A coordinated federal effort (from agencies including DCMS/DHA/VA) may provide enough demand to keep as many domestic suppliers alive as possible. The DoD made enormous investments in masks that could have been better spent elsewhere (mostly driven by poor decision-making with the wrong suppliers).
- We need a strategy to allow for all mask manufacturers to be on contract with a multi-agency multiple award, indefinite delivery, indefinite quantity contracts (MAC IDIQ) to get them all to be competitive on each buy, hopefully driving them to competitive prices in the future. Also, the DoD need to be aware of potential price gouging in a relationship where they know these small domestic manufacturers are being kept alive and become rent seekers; clearinghouses like Project N95 can help protect Government Procurement from exposure to price-gouging.
- OCEA could begin to mandate masks for grocery stores, meat packing facilities, and other areas where transmission is still an issue, and mandate use of local domestic mask manufacturers.
- Top distributors such as Cardinal and McKesson should bring on some domestic mask orders, and include these in their portfolio to GPO's and hospitals. Hospitals need to dedicate a portion of their buys to domestic manufacturers, as they were the most impacted by the PPE shortages.

Sadly, we believe the Strategic National Stockpile ship has sailed with the majority of their mask purchases already in place with foreign produced materials. But let's not repeat the same mistakes and let our domestic mask manufacturers fall into disarray. There is still time, with concerted and swift action, to correct course and ensure our ability to produce these critical goods domestically is secure.



### Is it possible to bring medical supply manufacturing back to America?

Something occurred on January 20<sup>th</sup> of this year that led to this shift in focus—Joe Biden was inaugurated as the 46<sup>th</sup> President of the United States and began signing a flurry of executive orders that have major implications for supply chain and contract management. Our focus for this column is E.O. signed on 25 January 2021, Executive Order entitled, *Ensuring the Future Is Made in All of America by All of America's Workers*, as part of his Build Back Better commitment to increase investments in U.S. manufacturing industries and workers<sup>1,2</sup>. Past and current policies have focused on preference for purchasing American made products, but we need to come to grips with the fact that many products (and some services) will need to be developed within domestic markets using a dovetailed approach to make this charge actionable by federal procurement offices. A dovetailed approach considers the reality that markets exist in a state today that may not make American solutions feasible, yet works towards bolstering the availability of domestic, Pan-American, and strategic global partnerships to optimize sourcing efficiency and effectiveness. That takes more than a 'buy' strategy...it takes a 'build' strategy based on our concept of Global Independence. No one is arguing about being unpatriotic – but

<sup>1</sup> [President Biden to Sign Executive Order Strengthening Buy American Provisions, Ensuring Future of America is Made in America by All of America's Workers | The White House](#)

<sup>2</sup> [Executive Order on Ensuring the Future Is Made in All of America by All of America's Workers | The White House](#)

we do need to grasp the reality of what 20 years of outsourcing to low cost economies has done to our economy and the structure of where we source most products today.

**Background: The Buy American Act**

The Buy American Act (BAA) was first signed into law in 1933 to respond to the Great Depression by restricting the public procurement of supplies that are not domestic end products<sup>3</sup>. The act covers end products, to include construction and some products supplied under a services contract. The key aspect of this legislation is its focus on the manufacturing source. For example, American goods sold by a foreign company are still considered domestic, while foreign-manufactured goods sold by an American company are not. There are plenty of exceptions.

The exceptions to the BAA may be determined by agencies on a case by case or blanket basis. These exceptions include:

BAA Exception	FAR Description	FAR written determination authority
Public interest	When domestic preference would be inconsistent with the public interest. This exception applies when an agency has an agreement with a foreign government that provides a blanket exception to the Buy American statute. (Most notably the World Trade Organizations Government Procurement Agreement <sup>4</sup> )	Head of agency or as delegated
Nonavailability	BAA does not apply with respect to articles, materials,	Head of agency or as delegated <sup>6</sup>

<sup>3</sup> [GAO-19-17, Buy American Act: Actions Needed to Improve Exception and Waiver Reporting and Selected Agency Guidance](#)

<sup>4</sup> The WTO GPA provides for the US and other GPA countries to compete foreign and domestic products on equal footing without the cost evaluation offsets prescribed by the FAR or similar foreign country regulations. An expansive list of WTO GPA and other trade agreement eligible criteria, evaluation concerns and thresholds can be found at FAR 25.4.

<sup>6</sup> Note: Federal-level class determinations for products deemed as non-available can be found at FAR 25.104 and are updated every 5 years.

	or supplies if articles, materials, or supplies of the class or kind to be acquired, either as end items or components, are not mined, produced, or manufactured in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality <sup>5</sup> .	
Unreasonable costs	The contracting officer may determine that the cost of a domestic end product would be unreasonable, in accordance with 25.105 and subpart 25.5.	Contracting Officer
Resale	The contracting officer may purchase foreign end products specifically for commissary resale.	No FAR requirement
Information technology that is a commercial item.	The restriction on purchasing foreign end products does not apply to the acquisition of information technology that is a commercial item, when using fiscal year 2004 or subsequent fiscal year funds (Section 535(a) of Division F, Title V, Consolidated Appropriations Act, 2004, and similar sections in subsequent appropriations acts).	No FAR requirement
Micro-purchases	BAA does not apply to procurements below the micro-purchase threshold (generally \$10,000) <sup>7</sup>	No FAR requirement

*Table 1: Buy American Act Exceptions from FAR Part 25*

#### **Recent Buy American and Domestic Resource Executive Actions**

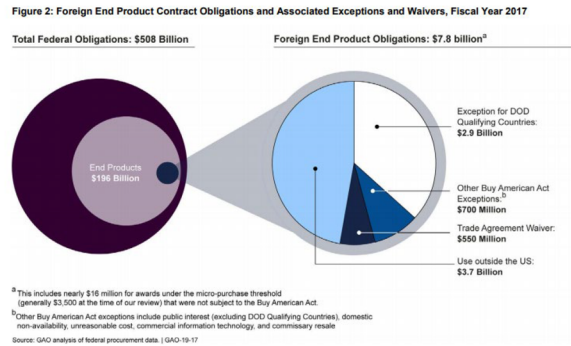
<sup>5</sup> Note: This can include that domestic sources can only meet 50 percent or less of total U.S. Government and nongovernment demand per FAR 25.103(b)(1)(i).

<sup>7</sup> Note: The micro-purchase thresholds can be found at FAR Part 2 and include certain exceptions such as construction (\$2,000), services (\$2,500), domestic contingencies (\$20,000) and contingencies abroad (\$35,000).

In April of 2017 then President Trump signed E.O. entitled, *Buy American and Hire American: Putting American Workers First* mainly focused on enforcing illegal immigration hiring restrictions. It did not address the procurement of American goods or services. President Trump also signed E.O. NO. 13953 in September of 2020 entitled, *Addressing the Threat to the Domestic Supply Chain From Reliance on Critical Minerals From Foreign Adversaries and Supporting the Domestic Mining and Processing Industries*. This E.O. seeks to increase vital mining and manufacturing for critical materials necessary to U.S. economic interests. The Trump administration took additional executive action to ban communication applications WeChat and TikTok and their owners as part of a supply chain security initiative in 2020<sup>8</sup>.

### Concerns

In April of 2020 the Trump administration sought to take additional executive action to bolster Buy American provisions. The Center for Strategic and International Studies provided a critique of the Trump policy citing concerns around increasing Buy American focus during the constraints and challenges posed by the pandemic. They noted a GAO study from 2018 that found that, based on current waivers and exceptions, only 5% of requirements are for foreign end products, many of them defense requirements for use outside the U.S. and therefore exempt from BAA entirely (See below figure)<sup>9</sup>.



<sup>8</sup> [Federal Register :: Addressing the Threat Posed by TikTok, and Taking Additional Steps To Address the National Emergency With Respect to the Information and Communications Technology and Services Supply Chain](#)

<sup>9</sup> [A World in Crisis: Will Buying American Help or Hurt? | Center for Strategic and International Studies \(csis.org\)](#)

Source: GAO-19-17, Figure 2, p. 14

This shows that only 2% of foreign goods are purchased via waiver or DoD exception. Any actions taken to increase the procurement of American made goods will have to look at other areas to improve. The main critique of the CSIS article is that impacting federal procurement will do little to assuage private market purchasing decisions that overwhelmingly drive the manufacturing and supply chain availability in the U.S., especially as it applies to healthcare and medical supplies and services. It also reflects the naïve nature of policy makers who do not understand the reality of global supply chain structures.

#### **Review of Biden E.O.<sup>10</sup>**

The current E.O. from the Biden administration has six overriding goals with a guiding principle to support America's workers through federal purchasing. These goals include:

- 1) Directs agencies to close current loopholes in how domestic content is measured and increase domestic content requirements.
- 2) Appoints a new senior leader in the Executive Office of the President in charge of the government's Made-in-America policy approach.
- 3) Increases oversight of potential waivers to domestic preference laws.
- 4) Connects new businesses to contracting opportunities by requiring active use of supplier scouting by agencies.
- 5) Reiterates the President's strong support for the Jones Act.
- 6) Directs a cross-agency review of all domestic preferences.

#### **Point 1: Close current loopholes and increase domestic requirements**

This action increases the domestic manufacturing percentage from 50% to 55% (95% for iron and steel products) and increases the price evaluation differential for non-domestic product evaluations<sup>11,12</sup>. This price differential is not defined within the E.O. The manufacturing percentage is further directed to move from a component-based test under FAR Part 25 to a total added value basis (also not defined). The primary concern here is that doing this will not drive an

<sup>10</sup> [President Biden to Sign Executive Order Strengthening Buy American Provisions, Ensuring Future of America is Made in America by All of America's Workers | The White House](#)

<sup>11</sup> [Biden turns to 'Buy American' law to aid US manufacturing - Roll Call](#)

<sup>12</sup> [Executive Order on Ensuring the Future Is Made in All of America by All of America's Workers | The White House](#)

increase in the availability of critical resources of supply or manufacturing. It is hard to imagine how much difference 5% will make for markets where no domestic source exists. In these cases, the government will have to establish other incentives for such firms to manifest. In many cases these markets require large capital investments over time and will need years to establish learning curves strong enough to overcome the vast difference in labor costs associated with overseas sourcing. We also have to be careful about unintended consequences. If the rule states that 55% of manufacturing component costs have to come from U.S. sources one could easily see profit motivated companies hitting this number domestically while still relying on cheap overseas labor and raw materials to offset their total manufacturing costs. If we increase the ratio it could lead to negative downstream impacts to global supplier workforce conditions. These assessments should be tied to value in terms of product outcomes as well as production resiliency. These changes won't solve the problem that we saw with the dearth of PPE and medical supplies needed for COVID response. Placing 55% of component costs in products made in America is either inefficient or a pipe dream for markets such as the N95 market that had 95% of production outside of the U.S. prior to 2020. The entire product value chain has to be assessed for all product and service categories deemed critical to national security (physical, economic and health). We can't place our goals on products costs, but instead on core components that present risks if their sources are disrupted. If cotton is not the most expensive component in manufacturing masks it doesn't matter, it becomes a keystone component for manufacturing to occur in the first place. It is also unclear how the procurement personnel are to treat their exception to BAA that allows them to determine a price so unreasonable as to choose an overseas source over a U.S. provider. The difference in many end items costs from overseas vs. domestic based on just labor rates makes a price reasonableness determination hard for most public buying agents. It will also likely require premium prices which may counter FAR regulations requiring lowest cost. Specific legislation may be needed to advocate priorities for domestic sourcing.

**Point 2: Executive Officer for Made-in-America**

This action seems to be the most promising. Gaining top-level buy in is critical to driving institutional change. This role seems to be quite broad at this time. We recommend that the Director of Made-in-America at OMB take a category management approach to instituting these

new BAA enforcement actions. Having a whole-of-government site picture will be necessary to implement all other lines of effort under this E.O. We recommend that the Director of Made-in-American work with the Office of Federal Procurement Policy (OFPP) to establish Buy-American advocates within each federal category and across each federal agency to keep abreast of products that are domestically available but not leveraged or to identify critical life support and sustainment markets wherein there is no domestic source of material or manufacturing (e.g. medical supplies, food, textiles, rare earth elements etc.).

**Point 3: Increase domestic waiver oversight**

We agree that having the GSA publish all existing waivers is important, however the waiver and exception provisions of FAR 25 are complex and confusing. We recommend that the Director of Made-in-America work with GSA to establish a natural language-enabled application that works similarly to TurboTax allowing procurement personnel to answer a string of basic questions that lead to a recommendation of “waived” or “not waived” with the associated link to said waiver. This system could be updated in real-time to ensure only necessary waivers are considered by public procurement personnel. There should also be some acknowledgement given to the fact that for certain industries, re-shoring is unlikely ever to happen. The costs of transferring an entire industry is too great, and no entity is likely going to take on the financial investment risks knowing full well that they will never be competitive. What if a new administration comes in 2024, and the payback on this investment is 10 years or more?

**Point 4: Supplier Scouting**

This is a very promising directive within the E.O. Essentially it is pointing to the use of robust and persistent market intelligence to enable agencies to become aware of nascent or opaque domestic sources of manufacturing via the Hollings Manufacturing Extension Partnership (MEP) in all 50 states and Puerto Rico. We cheer this action and again recommend the use of category management and coordination with OFPP as the best first steps for organizing this effort. We have previously written on the concept of orbital market intelligence to stay abreast of sourcing solutions with strategic focus on dwell times, revisit rates and resolution of category markets<sup>13</sup>.

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<sup>13</sup> Handfield R, Finkenstadt DJ, Schneller ES, Godfrey AB, Guinto P. A Commons for a Supply Chain in the Post-COVID-19 Era: The Case for a Reformed Strategic National Stockpile. *Milbank Q*.

We further recommend that the Director of Made in America consider the manufacturing capabilities incubated, grown and advanced by the university system (e.g. the advanced textile manufacturing capabilities at the N.C. State Wilson College of Textiles that responded in the early months of the pandemic with much needed nonwoven materials).

**Point 5: Support for the Jones Act**

We agree that the Jones Act should continue to be supported. The Jones Act is a federal law that regulates maritime commerce in the United States. The Jones Act requires goods shipped between U.S. ports to be transported on ships that are built, owned, and operated by United States citizens or permanent residents.

**Point 6: Cross agency review of domestic preference**

The concept of bi-annual reviews for potential domestic service and manufacturing opportunities seems reasonable. The E.O. calls for updates to the list of non-available articles at section 25.104(a) of the FAR and are report on information technology that is a commercial item. We encourage these reviews to consider how requirements are developed and defined. Demand management and requirements development are cornerstones of sound category management. Coupled with strong market intelligence, demand management can lead to novel solutions and novel solutions can open up areas of innovation that can increase domestic solution availability. For example, as part of a Hacking for Defense project, a team of MBA students at the Naval Postgraduate School recently presented Army Futures Command with a set of novel solutions to aid them in developing a strategy for advanced textiles that mapped the textile manufacturing value chain, identified the scope of textile products utilized by DoD/Army and existing and developmental automation and robotic assembly technologies. This included recommendations on the use of 3-D printing and nascent cut and sew automation to increase opportunities for domestic sourcing to meet Army needs. Such projects should be scaled across multiple categories within the OFPP portfolio in partnership with the Director of Made-in-America to identify new or emerging Buy American opportunities.

Some industries such as PPE already have a high potential for domestic growth, due to the existence of a textiles industry in the southeast, and infrastructure that is ready to adopt to these conditions. Other like pharmaceutical and biotech production already exist in the US and have the potential for growth. Finally DoD engineering staff should take care to seek industry-based specifications to maximize the likelihood that domestic manufacturers are not reliant just on DoD buyers for certain parts, and enable them to serve a larger market

**Post-Hearing Questions for the Record  
Submitted to Robert Handfield, Ph.D.  
From Senator Jon Ossoff**

**COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps  
Wednesday, May 19, 2021**

**Question:** Please submit for the record an itemized list of the medical equipment, products, precursors for production of key medical supplies and products, and the pharmaceutical products that may swiftly be in high demand and of which we may have shortages across a range of plausible public health crises so that this committee can refer to such list as we consider other supply chains that may require reinforcement.

As stated in my [earlier report for the IBM Business of Government \(Handfield, 2011\)](#) the U.S. medical system has been increasingly reliant on low cost manufacturing from overseas sources, a trend that has been occurring for the last thirty years. Much of this activity has been driven by the continued pressure of the healthcare system to buy pharmaceutical products and medical supplies at the lowest cost. Medical supplies include many of the items shown in Table 1 below, which includes surgical and N95 masks, gowns, latex gloves, catheters, single use tubing, Propofol, IV fluids bioreactor bags, and many other items. All of the products shown in Table 1 experienced significant supply shortages during the COVID crisis. Beginning as early as the 1970s many companies moved their manufacturing to low-cost regions to gain improved labor cost—often one of the highest contributors to the cost of goods sold. Offshoring was enabled by international trade agreements struck between nation states, reductions in duties and taxes and other government incentives. The offshoring of production often meant that firms established large, centralized, production facilities to exploit volume advantages, in locations such as China and India. Final products were manufactured in centralized facilities and then shipped around the globe to large distribution centers in the US and Europe. Many of the distributors of these products, including companies like Cardinal, McKesson, Owens and Minor, Premier, MedAssets, and others, bought them in large quantities at discounts, and then sold them in bulk to hospitals, based on contracts that promoted a “stack ‘em higher, buy ‘em cheaper” mentality. This practice was also encouraged by increased pressure on hospitals by CMS and private insurance companies to reduce patient costs. For products like nitrile gloves, there emerged near monopolies like Top Glove and Viet Glove in Vietnam.

For N95 masks, more than half of the world’s supply came from China, and in fact, much of that was produced in the Wuhan region where COVID originated! 3M also secured all of their raw materials for masks from China, and their factory there was directed to sell only within China by the government through April 2020.

In pharmaceuticals, as more common products became generic, many of the inputs for drugs, known as Active Pharmaceutical Ingredients were sourced from India, which then sources many of their materials from China. Manufacturing is outsourced to Contract Manufacturing Organizations (CMO’s) who are often evaluated based on a per unit price basis, and directed by brand pharmaceuticals to produce according to the “recipe” provided them using the suppliers they were directed to buy from.

There were inherent risks with buying low cost medical supplies and pharmaceuticals from Asia. First, there was a lack of direct control and oversight over operations, and the risk of GMP and quality problems

was significantly higher. Second, most shipments were made by ocean freight, and the leadtimes for such shipments became longer and longer, as the ships became larger and slower and made more frequent stops (again to save money and drive down the cost of transportation). Distributors in the US tried to keep inventory as low as possible, and tried to keep as little safety stock on hand as possible. Domestic manufacturers of medical products could not compete with these low costs, and many went under or transferred operations to Asia. The Chinese tariffs created further problems as supply became constrained. One of the biggest risks overlooked was the remote possibility that export controls or product shortages would cut off our supplies of medical supplies, a risk which in fact came to fruition in early 2020. Another risk I observed during my work with hospital supply chains is that they often had very poor inventory management practices, with little visibility to their current inventory levels, which we referred to in our paper "[Blurry Vision: Supply Chain Visibility for PPE during COVID](#)".

#### **An Appeal to Congress and the FDA: Act now, before U.S.-made PPE all but disappears**

In my recent [testimony](#) to the US Senate [Sub Committee on Homeland Security and Government Affairs](#) on May 19 (COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps), I emphasized the critical need for developing independence from global sourcing of healthcare products from China. I also emphasized in [a Harvard Business Review article](#) the dependency of the Strategic National Stockpile on foreign sources of personal protective equipment (PPE), the bulk of which came from China. This hearing was in support of two bills by the Senate, one of which is advocating development of local domestic sources for critical healthcare supplies.

In response to the pandemic and the resulting PPE crisis, many domestic manufacturers sprang into action. New entrants came into the market, working hard to fill the PPE gap. Many existing manufacturers extensively retooled production lines to produce N95 masks. They have gone through the process of having these masks approved by NIOSH, and the majority have been certified. These manufacturers are now seeing a massive drop in sales as they are [faced with a glut of Chinese masks](#) that are cutting them out of the business.

This has left many of them struggling to survive, with idled factories and workers receiving pink slips. As a board member of the non-profit Project N95, we have had numerous discussions with domestic mask manufacturers who have told us that they likely have 30 days or 60 days left, before they are unable to continue and must declare bankruptcy.

Have we learned anything from this pandemic? The data we have is clear. As shown in our analysis of Twitter data (below), the number of times that "PPE shortages" came up escalated in the March and April 2020 timeframe, and did not recede until December 2020. Industry responded to the call, establishing domestic production facilities capable of producing billions of certified N95 masks. Yet now our government seems unable to commit to supporting these domestic mask manufacturers.

The major pipeline for distribution of masks to hospitals is through the "Big Three" distributors: McKesson, Cardinal Health, and Amerisource Bergen. These distributors have told domestic manufacturers that their prices are not competitive – despite the fact that these same distributors were not able to supply the United States during COVID, as they were not able to get access to Chinese-made

masks. Even in the recent Presidential speech to Congress, members of Congress were seen on television, wearing Chinese-made KN-95 masks, which have the “folded ear straps” design, many of which have not been NIOSH certified. (see below).

Unless we all act fast, and unless the Feds do more than just introduce U.S. startups to McKesson & Cardinal Health (who won't stock these domestic suppliers at their current price-points) then these companies will all go belly-up.

Why is this happening? There are many factors at play, including issues around price. We would argue that value - particularly for pandemic contingency materials like PPE - is defined as affordable, reasonable, accessible and safe. The current approach our government is using only addresses short term affordability. It does nothing to ensure our ability to deliver accessible, safe materials in the future.

By letting small domestic manufacturers fall by the wayside we are potentially choosing to destabilize domestic healthcare and end-consumer supply of these critical masks for future pandemics or healthcare emergencies. The “future” may not be too distant, as more variants lead to localized shutdowns in the southern hemisphere. Letting domestic mask makers shutter their doors and go bankrupt this summer will only leave us more exposed by the fall as the risk of additional waves increases, as schools return to in-person instruction with only a portion of their populations vaccinated.

It's now that we have to consider the total cost of a supply chain strategy. Chinese goods may carry the lowest selling price when there is unlimited access to stock, but this low cost strategy can lead to complete supply chain impotence when faced with [barriers to access](#) as was seen during the early months of COVID in the US.

It is clear that the federal government is doing the bare minimum to create sustainable PPE supply - recent changes to [their mask mandate](#) failed to motivate anyone and the CDC only very recently updated guidance to allow health care facilities to return to conventional protocols -- meaning one use of a single-use N95.

The situation is similar for domestic manufacturers of rapid COVID-19 tests. While there was strong support for the research programs to create new tests, there is very little messaging on the importance of continued testing given the rise of variants. All of this has now left the domestic market quite stranded.

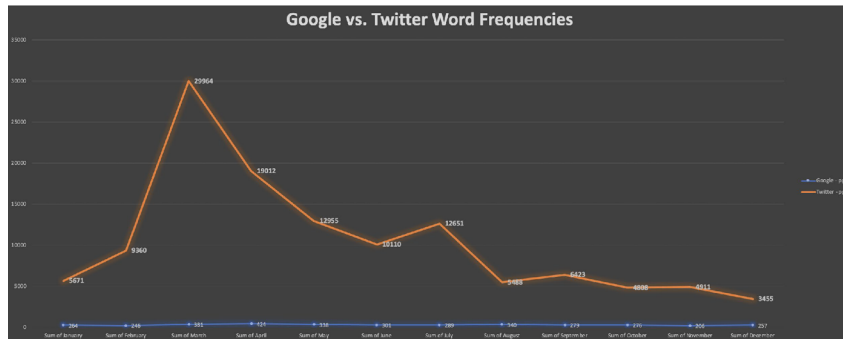
In light of the CDC messaging failures, the added failure of the federal government to properly prop up domestic mask manufacturers, and the hesitation to encourage disciplined testing with a concerted national message, there is an urgent need to act. What is needed?

- A coordinated federal effort (from agencies including DCMS/DHA/VA) may provide enough demand to keep as many domestic suppliers alive as possible. The DoD made enormous

investments in masks that could have been better spent elsewhere (mostly driven by poor decision-making with the wrong suppliers).

- We need a strategy to allow for all mask manufacturers to be on contract with a multi-agency multiple award, indefinite delivery, indefinite quantity contracts (MAC IDIQ) to get them all to be competitive on each buy, hopefully driving them to competitive prices in the future. Also, the DoD need to be aware of potential price gouging in a relationship where they know these small domestic manufacturers are being kept alive and become rent seekers; clearinghouses like Project N95 can help protect Government Procurement from exposure to price-gouging.
- OCEA could begin to mandate masks for grocery stores, meat packing facilities, and other areas where transmission is still an issue, and mandate use of local domestic mask manufacturers.
- Top distributors such as Cardinal and McKesson should bring on some domestic mask orders, and include these in their portfolio to GPO's and hospitals. Hospitals need to dedicate a portion of their buys to domestic manufacturers, as they were the most impacted by the PPE shortages.

Sadly, we believe the Strategic National Stockpile ship has sailed with the majority of their mask purchases already in place with foreign produced materials. But let's not repeat the same mistakes and let our domestic mask manufacturers fall into disarray. There is still time, with concerted and swift action, to correct course and ensure our ability to produce these critical goods domestically is secure.







OCEA: Office of Clinical Evidence and Analysis (OCEA)

**Response of Stephen W. Schondelmeyer, PharmD, PhD  
Co-Principal Investigator,  
Resilient Drug Supply Project, University of Minnesota to  
Post-Hearing Questions for the Record  
From Chairman Gary C. Peters**

**COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps  
Wednesday, May 19, 2021**

Thank you Chairman Peters for submitting Post-Hearing Questions for the Record. The responses to your three questions are provided below.

**1. How would you assess the federal government’s ability to coordinate and manage increasing drug supply shortages leading up to and during the initial pandemic response?**

The federal government has authority<sup>1</sup> to collect many types of information to assist in coordinating and managing the emergence and mitigation of drug shortages. Among the information that the FDA can request and collect are: (1) details about the process for manufacture of drug products and devices; (2) a list of the active and inactive ingredients used in the manufacturing process of a given drug product or device; (3) the registration of facilities (both domestic and foreign) where such drug products and devices are manufactured, prepared, propagated, compounded, processed, packaged, labeled, repackaged or relabeled; and (4) a list of specific drug or device products processed at each registered facility. The federal government assigns a unique identification number for each drug product or device and for each registered facility.

The information itemized above should have provided the federal government with the ability to build a comprehensive upstream supply chain map for drug products and devices sold in the U.S. market. However, for the information listed above, it is not clear: (1) if all of the information is actually collected by FDA; (2) how the various types of collected information are stored and accessed; (3) the extent to which the information is, or can be, integrated internally or with other data; and (4) if the information can be used to assess the overall market capacity and vulnerabilities in drug supply chains or the actual quantities of product available in the U.S. market.

The FDA points out that it lacks information that would be needed to assess if, and how quickly, “U.S.-based manufacturers [can] increase their production of APIs [or finished dose forms] to meet domestic demand if China or India, or another country, ceased supplying the United States.”<sup>2</sup> Furthermore, on October 30, 2019—just 2 or 3 months before the COVID-19 outbreak—the FDA testified before Congress that “we do not have information that would enable us to assess

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<sup>1</sup> 21 U.S. Code §360 and other statutes and regulations.

<sup>2</sup> Janet Woodcock, Safeguarding pharmaceutical supply chains in a global economy. Testimony of Janet Woodcock, MD, Director of the Center for Drug Evaluation and Research, Before the House Committee on Energy and Commerce, Subcommittee on Health, Oct 30, 2019.

the resilience of the U.S. manufacturing base, should it be tested by China's withdrawal from supplying the U.S. market.”<sup>3</sup>

Among the other types of information needed regarding drug products, and which are not now readily available to the federal government, are: (1) the total and unused manufacturing capacity (both quantities and types of products) of U.S.-based and all registered foreign facilities; (2) the time required to produce additional quantities of needed drug products by U.S.-based and all registered foreign facilities; (3) comparison of quantities of drug products that can be produced by increased U.S.-based production versus increased quantities needed due to demand from a pandemic or decreased quantities resulting from a reduction in drug product supplied by China, India, or another country; and (4) how long would it take to increase, build, or re-shore the needed production and what other incentives would be needed to make such production sustainable for the pharmaceutical industry.

***The federal government needs authorization and appropriation to collect, coordinate and manage additional information to better facilitate the prediction, prevention, management, and mitigation of drug shortages.***

While the FDA has the authority to, and actually does, collect and use certain information related to the manufacture and marketing of drug products to manage drug shortages, the issue of drug shortages has continued to be a substantial problem in the United States. The FDA Drug Shortage Staff have been managing and coordinating the FDA's drug shortage activities in recent years. In the past four years (2017 to 2020), the annual number of new drug shortages grew by 10.3% from 39 to 43 new drug shortages.<sup>4</sup> Fortunately, during the same period (2017 to 2020), the annual number of FDA-prevented drug shortages increased by 37.2% from 145 to 199 prevented drug shortages. These results are to be commended. The net result, however, is that the annual number of ongoing drug shortages as reported by the FDA has more than doubled in the last four years with an increase of 109.8% from 41 to 86 ongoing drug shortages from 2017 to 2020. *Both the absolute level of drug shortages (86) and the rate of growth (109.8%) in ongoing drug shortages are unacceptable results with respect to their impact on the health of U.S. patients.*

In order to minimize drug shortages, both before and during the pandemic, the federal government's ability to coordinate and manage the increasing drug supply shortages required not only additional information, but also cooperation and the ability to share information across a number of federal agencies and with other stakeholders and academic researchers. Early in the emergence of the pandemic (mid-January 2020), several federal agencies began to meet and work together to anticipate and estimate the potential impact of the pandemic on the U.S. drug supply. Among the issues that arose with regard to coordination of drug shortage policy issues was: (1) which agency would take the lead in drug shortage policy and planning efforts; (2) what information did various government entities have to address drug shortage issues; (3) whether the federal agencies could share information across agencies or with appropriate stakeholders or

<sup>3</sup> Woodcock, Testimony Before the House Committee on Energy and Commerce, Subcommittee on Health, Oct. 30, 2019.

<sup>4</sup> U.S. FDA, Report to Congress, Drug Shortages for Calendar Year 2020. Accessed on July 3, 2021 at: <https://www.fda.gov/media/150409/download>.

academic researchers; and (4) how could information be securely shared and coordinated across federal agencies and with appropriate stakeholders and academic researchers.

The Secretary of Health and Human Services (HHS), acting through the Commissioner of Food and Drugs (and the FDA) has authority to collect specific and detailed information regarding drug manufacture and marketing in order to ensure the quality and availability of drug products in the U.S. market. Among the data collected by FDA is information that could be used to anticipate, predict, monitor, and mitigate drug shortages in the market. A number of other federal agencies have information on drug use, demand, or purchasing including: (1) the Centers for Medicare and Medicaid Services (CMS) with data from the Medicaid and Medicare programs; (2) the Veterans Administration (VA) with data from the VA hospitals and clinics that serve America's veterans; (3) the Department of Defense (DOD) with data from facilities serving America's war fighters as well as their families and dependents; (4) the Department of Administration's Federal Employee Health Benefit Program serving federal employees and their families and dependents; and (5) a number of other federal agencies. Other federal agencies have some insight and responsibility related to federal policy that can influence the market for drugs and related drug shortages issues, including, but not limited to: (1) the Federal Trade Commission; (2) the Department of Commerce; (3) the U.S. Trade Representative; (4) the DHHS Assistant Secretary for Preparedness and Response; (5) the Assistant Secretary of Defense for Health Affairs; (6) the National Security Advisor to the Secretary of Health & Human Services, (7) the Department of Homeland Security; (8) the Biomedical Advanced Research and Development Authority (BARDA); (9) the Federal Emergency Management Agency (FEMA); (10) the U.S. Department of the Treasury; (11) the Drug Enforcement Administration (DEA) within the U.S. Department of Justice; and (12) other federal agencies.

***The federal government needs explicit authorization to share drug manufacturing and drug shortage-related information across federal agencies and with appropriate stakeholders and academic researchers in order to facilitate timely management, coordination and planning for prediction, mitigation, and elimination of drug shortages in the United States.***

Senate bill 3781, known as the "Pharmaceutical Accountability, Responsibility, and Transparency Act" or the "PART Act", addresses both the authority for FDA to collect additional information related to the drug supply chain and drug shortages; and, it authorizes the sharing of information across federal agencies for the following purposes: (1) Maintaining the strategic national stockpile under section 319F-2 of the Public Health Service Act (42 U.S.C. 247d-6b); (2) Evaluating health infrastructure under the Division of Critical Infrastructure Protection of the Office of the Assistant Secretary for Preparedness and Response; (3) Preparing for and responding to public health emergencies and national security concerns; and (4) Mitigating potential drug shortages.

Based upon the above-described situation, the federal government's ability to coordinate and manage increasing drug supply shortages during the continued pandemic environment and beyond would be enhanced with the passage of legislation incorporating the principles set forth in the PART Act. This legislation would provide authorization for collection of additional relevant information and authorization to share that information across appropriate federal agencies and with approved stakeholders and academic researchers. The provisions outlined in the PART Act,

with revisions as suggested in this response, should be passed to better facilitate the prediction, prevention, management, and mitigation of drug shortages.

In summary, Congress should enact legislation with provisions that accomplish the recommendations shared during my oral and written testimony before the Senate Committee on Homeland Security and Government Affairs on May 19, 2021.<sup>5</sup> First, the United States should have a defined process and infrastructure for analyzing, predicting, managing, and preventing shortages of critical medications. Second, an in-depth map of the U.S. drug supply chain is needed and should be maintained on an ongoing basis to facilitate planning for, and management of, market distorting events of any kind. Third, Congress should designate, authorize, and fund a national entity to build and maintain the U.S. drug supply chain map, to make the drug supply chain and its quality more transparent, and to coordinate development of relevant national policy to strengthen and improve the resilience of the U.S. drug supply chain as it faces future threats of all kinds. Finally, the U.S. needs to establish an ongoing research program on resilience of the U.S. drug supply chain including a sentinel system that can “predict and prevent” drug shortages from supply chain disruptions and can coordinate a national response to drug shortages if, and when, they do occur.

“With the support of policymakers and cooperation of the FDA, other federal entities, and industry stakeholders, the U.S. can significantly reduce or eliminate drug shortages. Only then can we ensure a resilient supply of needed medications for the American population.”<sup>6</sup>

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<sup>5</sup> Stephen W. Schondelmeyer, *Strategic Assessment of the Resilience of the U.S. Drug Supply with Lessons from the Pandemic & Recommendations for Moving Beyond*, Senate Hearing on COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps, Written and Oral Testimony of Stephen W. Schondelmeyer before the Senate Committee on Homeland Security and Governmental Affairs, May 19, 2021.

<sup>6</sup> Schondelmeyer, *Written Testimony* submitted to the Senate Committee on Homeland Security and Governmental Affairs, May 19, 2021.

**2. What do you see as the most critical national security risks from our over-reliance on foreign sources for key starting materials, active pharmaceutical ingredients, and critical drugs?**

Responding to this question can be facilitated with discussion of several concepts: (1) the most critical national security risks; (2) over-reliance on foreign sources; (3) identification of critical or essential drug products; and (4) the stage of the upstream drug production process involved such as key starting materials (KSM), active pharmaceutical ingredients (API), and finished dose forms (FDF).

Vulnerabilities in the U.S. drug supply chain have been present for decades, but they became more noticeable during the pandemic. Among the critical vulnerabilities of the U.S. drug supply chain are: (1) heavy dependence upon foreign sources for drug production; (2) geographic and economic concentration in certain markets; (3) a shift from in-house manufacturing to a general contractor model of drug production; (4) challenges with inspection and quality control in foreign manufacturing facilities; (5) chronic quality problems in certain sectors (e.g., sterile injectables); (6) lack of upstream visibility by purchasers, policymakers and key stakeholders; (7) lack of a nationally coordinated policy approach to the pharmaceutical market; (8) misaligned regulatory and economic incentives in the pharmaceutical market; (9) old factories, equipment, and outdated manufacturing processes; (10) just-in-time inventory control rather than surge management of slack resources for resilience; and (11) below margin prices for older, well-established generics due to ‘over-competition’.

In general, the production of pharmaceuticals in foreign countries is not necessarily a bad thing. However, the current level of U.S. reliance or dependence on foreign sources, especially for certain critical or essential drugs, is concerning. Reliance on foreign sources for drugs is present when the current drug therapy needs of the U.S. market cannot be met without relying on one or more foreign sources of the drug product to supply sufficient quantities to meet market demand. Over-reliance on foreign sources results when the U.S. must acquire a substantial portion (i.e., >50%) of its drug demand from one or more foreign sources of production. Certainly, over-reliance can be present when a drug product is produced only at a single facility regardless of whether that facility is in the U.S. or a foreign country. If a foreign source of production is present at any stage in the upstream supply chain (i.e., KSMs, APIs, or FDFs), then the resulting product is considered to have come from a foreign source.

When there is only one non-U.S. source in the world for a drug product (or its KSM or API or FDF), there is over-reliance on that foreign source. The U.S. drug supply chain can be over-reliant upon foreign sources in general, foreign sources in a specific geographic region, foreign sources in a specific country, or even a specific foreign production facility. The U.S. drug supply chain is over-reliant on foreign sources when it must obtain more than 50% of the U.S. demand for that drug product from foreign sources.

The geographic sources for production of U.S.-consumed pharmaceuticals have transitioned dramatically over the past three decades (i.e., 1990 to 2020). Historically, the United States has been the home base for drug companies that conduct research to discover, develop, and market pharmaceutical products. Several decades ago, most drug products were actually made in the United States or its territory—Puerto Rico. In the late 1980s and early 1990s, a concentration of

pharmaceutical manufacturing facilities developed in Puerto Rico in response to the Puerto Rican Economic Activity Tax Credit (PREAC). To qualify for this credit a firm had to derive at least 80% of its overall gross income from business operations in one or more of the U.S. territories.<sup>7</sup> The drug industry responded to this PREAC tax credit by setting up substantial manufacturing operations primarily in Puerto Rico. A total of 26 drug firms owned manufacturing operations in Puerto Rico in 1990 and these facilities produced 80.1% or 17 of the 21 most commonly prescribed brand name drugs at the time.<sup>8</sup> In contrast, over thirty years later (i.e., 2021) the share of the top drug products made in the U.S. (including Puerto Rico) had shrunk to 20% or less.<sup>9</sup>

Research at the University of Minnesota's Resilient Drug Supply Project has found that about 80% (24 of 30) of the top 30 brand name drug products have finished dose forms that are made in foreign countries with 4 of the 6 U.S.-made brand names being produced in Puerto Rico.<sup>10</sup> Similarly, about 80% of the top 30 generic drug products have finished dose forms that are made outside of the U.S. When examining the source of APIs for these top brand and generic drug products, we found that about 90% of the API is made in foreign countries.<sup>11</sup> Most of the top brand name drug products are made in various European countries, while most of the top generic drug products are made in India or China.

The FDA reports that 72% of API manufacturing facilities are located outside of the U.S. with 18% of the facilities in India and 13% in China.<sup>12</sup> Several reasons are cited to explain this shift from U.S. to foreign production for pharmaceutical manufacturing including relaxed environmental standards, lower labor costs, and the need for large multi-facility manufacturing and industrial sites.<sup>13</sup> The FDA acknowledges that the "pharmaceutical sector relies heavily on foreign sourcing [of] critical components, materials, and finished products".<sup>14</sup> The U.S. drug supply chain for both brand name and generic drug products is heavily dependent upon foreign sources.

There are several types of critical national security risks that may result from over-reliance on foreign sources for the U.S. drug supply including, but not limited to: (1) serious quality problems

<sup>7</sup> Gary Guenther, *Federal Taxation of the Drug Industry and Its Effects on New Drug Development*, Congressional Research Service, March 18, 2009, p.

<sup>8</sup> U.S. General Accounting Office, *Pharmaceutical Industry: Tax Benefits of Operating in Puerto Rico*, GAO report GGD-92-72BR (Washington: May 1992), pp. 4-7.

<sup>9</sup> Stephen W. Schondelmeyer, "Improving Resilience & Reducing Shortages in the Drug Supply Chain: Roles of the USP, CIDRAP & Others," presented to the USP Council of the Convention, May 12, 2021, p. 18; this document is Appendix D attached to "Strategic Assessment of the Resilience of the U.S. Drug Supply with Lessons from the Pandemic & Recommendations for Moving Beyond", Senate Hearing on COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps, Written Testimony of Stephen W. Schondelmeyer before the Senate Committee on Homeland Security and Governmental Affairs, May 19, 2021.

<sup>10</sup> Schondelmeyer, Written Testimony, Appendix D, May 19, 2021.

<sup>11</sup> Schondelmeyer, Written Testimony, Appendix D, May 19, 2021.

<sup>12</sup> Janet Woodcock, *Safeguarding pharmaceutical supply chains in a global economy*. Testimony of Janet Woodcock, MD, Director of the Center for Drug Evaluation and Research, Before the House Committee on Energy and Commerce, Subcommittee on Health, Oct 30, 2019, p. 2.

<sup>13</sup> U.S. Food and Drug Administration, "Pathway to Global Product Safety and Quality External Link Disclaimer," A Special Report, p. 20. Accessed October 4, 2019.

<sup>14</sup> U.S. Department of Commerce, Office of Technology Evaluation, *Reliance on Foreign Sourcing in the Healthcare and Public Health (HPH) Sector: Pharmaceuticals, Medical Devices, and Surgical Equipment*, December 2011, accessed July 7, 2021.

with drug products in the U.S. market; (2) opportunities for foreign countries to have substantial economic and political leverage over the United States; and (3) continued presence of critical drug shortages in the U.S. market.

First, the quality of the U.S. drug supply may be at risk from over-reliance on foreign sources of drug production. Historically, the FDA has not been able to inspect foreign-based plants with either the frequency or the candor that has been used when inspecting U.S. plants.<sup>15</sup> There have been serious concerns with quality in foreign-based plants that do not have the same level of regulatory oversight as U.S.-based factories.<sup>16</sup> This ineffective oversight of quality in foreign facilities has resulted in serious incidents such as “dozens of deaths and hundreds of adverse reactions” in patients using contaminated heparin.<sup>17</sup> Another major quality consequence from ineffective oversight of quality in foreign facilities has been the initial failure to detect NDMA in drug products and the continued widespread recalls of important drug products resulting from presence of NDMA.<sup>18</sup> Drug products that have been contaminated and/or recalled due to NDMA include commonly used treatments for hypertension, ulcers, diabetes, tuberculosis, and smoking cessation.<sup>19</sup>

Second, U.S. over-reliance on foreign sources of drug production can provide foreign countries with opportunities for substantial economic and political leverage over the United States. Depending upon the philosophy, ethics, and politics of other countries that have a dominant position in drug production for certain therapeutic categories, the United States could find itself held hostage economically or politically over access to critical or essential drugs.<sup>20</sup> Recent data shows that the U.S. is heavily dependent upon foreign sources for much of our domestic prescription drug supply.<sup>21</sup> China, for example, makes “nearly all” supplies of penicillin G and about 80% of the world’s supply of many antibiotics.<sup>22</sup> China’s dominance in the antibiotic market is particularly concerning because in March of 2020 China hinted that it might impose export

<sup>15</sup> United States Government Accountability Office, Statement of Mary Denigan-Macauley, Director, Health Care, Testimony before the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, Committee on Appropriations, House of Representatives, March 4, 2021, GAO-21-409T.

<sup>16</sup> Katherine Eban, *Bottle of Lies: The Inside Story of the Generic Drug Boom*, New York, NY: Harper Collins, 2019.

<sup>17</sup> ABC News, FDA: Contaminated Heparin Found in 10 Countries, April 21, 2008; see, Janet Woodcock, Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, April 21, 2008, news conference; see also, prepared statement, Scientific Protein Laboratories, Waunakee, Wisc, April 21, 2008.

<sup>18</sup> David Keire, Dongmei Lu, U.S. FDA, CDER, Office of Pharmaceutical Quality, FDA’s Overview of the Guidance for Industry: Control of Nitrosamine Impurities in Human Drugs, FDA Small Business & Industry Assistance Conference 2020, October 2, 2020.

<sup>19</sup> NDMA has been found in commonly used treatments for hypertension [valsartan (Diovan), losartan (Cozaar), irbesartan (Avapro), olmesartan (Benicar), eprosartan (Teveten)]; ulcers [ranitidine (Zantac), nizatidine (Axid)]; diabetes [metformin (Glucophage)]; tuberculosis [rifampin (Rifadin, Rimactane), rifapentine (Priftin)]; and smoking cessation [varenicline (Chantix)]. See David Keire & Dongmei Lu, FDA, Overview of Guidance for Industry: Control of Nitrosamine Impurities in Human Drugs, October 2, 2020.

<sup>20</sup> Harris G, Palmer AW. China has near-total control of the world’s antibiotic supply. Is America at risk as a result? *STAT*, Apr 28, 2020.

<sup>21</sup> Schondelmeyer, Written Testimony submitted to the Senate Committee on Homeland Security and Governmental Affairs, Wednesday, May 19, 2021.

<sup>22</sup> Harris G, Palmer AW. China has near-total control of the world’s antibiotic supply. Is America at risk as a result? *STAT*, Apr 28, 2020.

controls on shipments of life-saving drugs to the US market, although it did not take that step at the time.<sup>23</sup>

Other countries, such as India, have placed export bans on specific drug products to protect the supply for their own country's use. Indian drug makers rely heavily (about 70%) on China for key starting materials, like benzene, as well as APIs. Due to the impact of COVID-19 many of these Indian drug makers experienced delays in receiving the ingredients from China to make finished generic drug products for the global market.<sup>24</sup> Consequently, in early March of 2020 the Indian government was so concerned about having enough critical drugs to meet the needs of the Indian market that it restricted the export of 26 APIs and finished drug products to prevent shortages in India.<sup>25</sup> As noted in my written testimony, the "drugs on India's export ban list accounted for about 10% of India's total pharmaceutical exports and included acetaminophen, metronidazole, erythromycin, clindamycin, and several essential vitamins.<sup>26</sup> India later prohibited the export of hydroxychloroquine because domestic stocks were running low and it wanted to first fulfill its own requirements.<sup>27</sup> As another example, the United Kingdom imposed trade limitations and an export ban on parallel export of 82 drugs, including insulin, amoxicillin, and acetaminophen."<sup>28,29</sup>

In general, the U.S. has an over-reliance on foreign sources for prescription drug products. About 87% of the API manufacturers making generic drugs for the U.S. market are located in foreign countries,<sup>30</sup> including 29% in India, 27% in the European Union and 16% in China.<sup>31</sup> Most drug products in the U.S. market are made in part, or wholly, by facilities outside of the United States. In some cases, countries like China control a very large share of the market for a specific drug product or therapeutic category (e.g., about 80% of the antibiotics market). If the U.S. has an over-reliance on a single foreign source for one or more critical drugs, that foreign country could use the over-reliance as a means of economic or political leverage over the U.S. If such a threat is acted upon by a foreign country, it could result in a drug shortage that would leave many Americans without a critically needed drug and could impact the public health of many Americans.

The U.S. needs to construct a detailed U.S. drug supply map of the upstream supply chain to monitor for over-reliance on specific foreign sources that pose the greatest risk. This supply chain map should also be used to determine drug products (FDF, API and KSM) at risk of developing into a drug shortage. The drug supply map should track: (1) the total share of drug products from any foreign source and the share from each country; (2) the characteristics of each foreign country

<sup>23</sup> Chakraborty B. China hints at denying Americans life-saving coronavirus drugs. Fox News. Mar 19, 2020.

<sup>24</sup> Chandna H. India to curb export of antibiotics, vitamins as coronavirus crisis hits supplies from China. The Print. Feb 20, 2020.

<sup>25</sup> PTI, BloombergQuint. India restricts drug exports as threat of coronavirus rises. Mar 3, 2020.

<sup>26</sup> PTI, BloombergQuint. India restricts drug exports as threat of coronavirus rises. Mar 3, 2020.

<sup>27</sup> Ghangurde A. India bars exports of hydroxychloroquine with some exceptions. Pink Sheet. Mar 25, 2020.

<sup>28</sup> Wallace D. UK blocks 82 from parallel export. Generics Bulletin, Mar 20, 2020

<sup>29</sup> Schondelmeyer. Written Testimony submitted to the Senate Committee on Homeland Security and Governmental Affairs, May 19, 2021.

<sup>30</sup> U.S. FDA, Testimony before the House Committee on Energy and Commerce, Subcommittee on Health regarding "Safeguarding Pharmaceutical Supply Chains in a Global Economy," October 30, 2019, <https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019>.

<sup>31</sup> Yangzong Huang, "U.S. Dependence on Pharmaceutical Products from China," August 14, 2019, Council on Foreign Relations Blog, <https://www.cfr.org/blog/us-dependence-pharmaceutical-products-china>.

with respect to geography, trade relations, and political perspective; (3) the ability to conduct objective facility inspections and to provide quality assurance in each country; and (4) other strategic considerations regarding the U.S. drug supply.

Some re-shoring of pharmaceutical production may be warranted and can be beneficial economically and logistically. Re-shoring pharmaceutical production provides several opportunities. First, re-shoring can reduce risks from foreign dependence in the U.S. drug supply chain. Second, re-shoring can encourage new production facilities to be built in America. Third, as companies re-shore production to America they should be encouraged to invest in modern technology that incorporates continuous manufacturing. The FDA supports “the adoption of modern manufacturing technology as a foundation for improving the overall quality of products.”<sup>32</sup> FDA expects that “adopting continuous manufacturing for pharmaceutical production will reduce drug product quality issues, lower manufacturing costs, and improve availability of quality medicines to patients.”<sup>33</sup>

As re-shoring is being encouraged and incentivized, we must also remember that not all U.S.-based production will automatically be of high quality or free from concerns. For example, the vaccine production plant operated by Emergent BioSolutions in Baltimore, MD has been contracted to make the J&J COVID-19 vaccine. However, this plant has been the subject of continuing product quality and manufacturing problems and was cited last year, after an inspection by the FDA, for human, process, and facility errors. The quality problems at Emergent BioSolutions led to the rejection of more than 15 million doses of the J&J COVID-19 vaccine.<sup>34</sup> Also, as we bring more production back to the U.S., we must remember that diverse geographic locations even within a country such as the U.S. may be more resilient, since specific events can affect an entire geographic region. For example, Hurricane Maria devastated Puerto Rico in 2017 and disrupted the supply of large volume parenterals (IV fluids) to hospitals across the United States.<sup>35</sup>

Senate bill 3780, known as the “Help Onshore Manufacturing Efficiencies for Drugs and Devices Act” or the “HOME Act” addresses provision of grants and loans to encourage investment in domestic advanced manufacturing for critical drugs and devices and to support for long-term, high volume government contracts to purchase critical drugs and devices in order to reduce the risk of foreign dependence in the U.S. drug supply chain. Based upon the above-described pharmaceutical manufacturing environment in the United States market, the policies included in the HOME Act would benefit the U.S. drug supply by reducing the risk from foreign dependence and by improving the quality of drug production and drug products in the U.S.

Congress should work with the FDA, the pharmaceutical industry, and purchasers to improve the resilience of the U.S. drug supply chain. This improvement can come from upgrading and

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<sup>32</sup> U.S. Food and Drug Administration, Quality Considerations for Continuous Manufacturing, Draft Guidance for Industry, February 2019, accessed July 7, 2021.

<sup>33</sup> U.S. FDA, Quality Considerations for Continuous Manufacturing, February 2019, accessed July 7, 2021.

<sup>34</sup> Jill Wechsler, FDA Shuts Down Emergent Vaccine Facility, April 20, 2021, accessed on July 3, 2021 at: <https://www.pharmtech.com/view/fda-shuts-down-emergent-vaccine-facility>; See, also, Emergent BioSolutions Hit with FDA Form 483, April 21, 2021, BioPharm International.

<sup>35</sup> Katie Thomas, US. Hospitals Wrestle With Shortages of Drug Supplies Made in Puerto Rico, The New York Times, Oct. 23, 2017.

renewing the domestic production capacity with modern continuous manufacturing processes that are environment-friendly and lower cost. At the same time, these manufacturing improvements can improve the quality of the drug products in the domestic market. The U.S. drug supply chain can become more resilient and less reliant upon highly concentrated foreign sources of supply, thus reducing the risk of adversarial leverage over the critical medicines that are essential to the health of the American public. Each of these steps should lead to a U.S. drug market with fewer drug shortages and better access to the critical medications that they need.

**3. At the beginning of the pandemic, the Food and Drug Administration contacted more than 180 drug manufacturers to request that they evaluate their supply chains for materials manufactured abroad. How did the federal government’s lack of visibility into the upstream pharmaceutical supply chain impact the federal response to COVID-19?**

The FDA is to be commended for taking action early (February 2020) in the pandemic to assess foreign (and China) vulnerability of the supply chain for key drugs.<sup>36</sup> During the month long period from January 24, 2020 to February 27, 2020, the FDA contacted 180 manufacturers of human drugs to remind them of applicable legal requirements for notifying the FDA of any anticipated supply disruptions.<sup>37</sup> The FDA also asked manufacturers to “evaluate their entire supply chain, including active pharmaceutical ingredients ... and other components manufactured in China.”<sup>38</sup>

About 20 drugs were identified which have either their API or finished dose form made solely in China. One manufacturer provided an alert to the FDA regarding a shortage of a human drug. The shortage was due to the impact of the coronavirus on workers at the manufacturing site for the active pharmaceutical ingredient (API). In this case, other therapeutic alternatives could be used by patients for the drug product in shortage and the FDA worked with the manufacturer to mitigate the shortage.

Presumably FDA gathered useful information through contact with 180 manufacturers requesting that they evaluate their supply chains for vulnerabilities related to materials used in producing pharmaceuticals. This action, however, highlights the federal government’s lack of visibility into the upstream supply chain. The lack of upstream visibility means that when a challenge to the U.S. drug supply occurs, such as a pandemic, we start scrambling to determine what the supply chain looks like and where there are vulnerabilities. Not only does this divert time and attention from managing the challenge (e.g., the pandemic), but it also means that Americans could be at risk of not having essential medications available when they need them.

The FDA receives information from the manufacturer when a drug product is first approved, including the potential sources of API and locations of finished dose form (FDF) manufacture that may be used by the sponsor to produce the approved drug product. However, a company may list several potential sources of API and may shift across these potential sources without notifying the FDA. As the FDA has reported to Congress: “Since we do not currently know whether API manufacturing facilities are actually producing the drug, or in what volume, or what portion of U.S. drug consumption is dependent on APIs from China or India, or another country, we cannot perform a reliable gap analysis.”<sup>39</sup>

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<sup>36</sup> Stephen M. Hahn, Commissioner of Food and Drugs, Food and Drug Administration, FDA Statement: Coronavirus (COVID-19) Supply Chain Update, February 27, 2020. Accessed on May 15, 2021 at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-supply-chain-update>.

<sup>37</sup> Hahn, FDA Statement, February 27, 2020.

<sup>38</sup> Hahn, FDA Statement, February 27, 2020.

<sup>39</sup> Janet Woodcock, Safeguarding pharmaceutical supply chains in a global economy. Testimony of Janet Woodcock, MD, Director of the Center for Drug Evaluation and Research, Before the House Committee on Energy and Commerce, Subcommittee on Health, Oct 30, 2019, p. 4.

FDA acknowledges that it “has no visibility into which API supplier an FDF manufacturer uses at any given time.”<sup>40</sup> In other words, the FDA does not necessarily know which source of API a finished dose form manufacturer uses to make drug product for the U.S. market.

Not only is the FDA’s upstream supply chain visibility limited, but also the manufacturers themselves may not have assessed the “vulnerabilities of their manufacturing supply chain” or developed plans to address them.<sup>41</sup> FDA points out that: “Currently, many medical product manufacturers lack plans to assess and address vulnerabilities in their manufacturing supply chain. . . .”<sup>42</sup> FDA has recommended that it be given authority “enabling FDA to require application holders of certain drugs to conduct periodic risk assessments to identify the vulnerabilities in their manufacturing supply chain (inclusive of contract manufacturing facilities), and develop plans to mitigate the risks associated with the identified vulnerabilities.”<sup>43</sup>

Although individual manufacturers have the closest view of their own supply chains, the supply chain vulnerabilities for the U.S. market, as a whole, are greater than the sum of the supply chains for these individual drug products. *The federal government should develop a comprehensive, in-depth map of the U.S. drug supply chain for prescription drug products. This map “should be maintained on an ongoing basis to facilitate planning for, and management of, market distorting events such as pandemics, weather events, man-made disasters, political and hostile threats and other situations that may arise.”*<sup>44</sup>

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<sup>40</sup> Woodcock, Testimony Before the House Committee on Energy and Commerce, Subcommittee on Health, Oct 30, 2019.

<sup>41</sup> Hahn, FDA Statement, February 27, 2020.

<sup>42</sup> Hahn, FDA Statement, February 27, 2020.

<sup>43</sup> Hahn, FDA Statement, February 27, 2020.

<sup>44</sup> Stephen W. Schondelmeyer, Strategic Assessment of the Resilience of the U.S. Drug Supply with Lessons from the Pandemic & Recommendations for Moving Beyond, Senate Hearing on COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps, Written and Oral Testimony of Stephen W. Schondelmeyer before the Senate Committee on Homeland Security and Governmental Affairs, May 19, 2021, p. 13.

**Post-Hearing Questions for the Record  
Submitted to Stephen Schondelmeyer, Pharm.D., Ph.D.  
From Senator Jon Ossoff**

**COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps  
Wednesday, May 19, 2021**

**Question:**

**Please submit for the record an itemized list of the medical equipment, products, precursors for production of key medical supplies and products, and the pharmaceutical products that may swiftly be in high demand and of which we may have shortages across a range of plausible public health crises so that this committee can refer to such list as we consider other supply chains that may require reinforcement.**

Thank you Senator Ossoff for submitting a Post-Hearing Question for the Record. Your question is an important and expansive request that will be answered to the best of our knowledge, given what we know today. However, the information you requested is, and should continue to be, the focus of ongoing research and analysis of market conditions related to the U.S. drug market and its potential vulnerabilities, particularly in the upstream drug supply chain. This response to your request is based upon the work of the team for the Resilient Drug Supply Project at the University of Minnesota and has benefited from productive collaborations with others, and draws upon extensive data from private and public sources including publicly available data from FDA.

First, let me define the scope of the lists of products that are included in the appendices to this response. The Resilient Drug Supply Project has focused on mapping the upstream supply chain for prescription drug products used by humans that are marketed in the United States. In particular, our work so far has predominantly examined the upstream drug supply chain from key starting materials (KSMs) to active pharmaceutical ingredients (APIs) to finished dose forms (FDFs) to prescription drug products marketed in the U.S., and all steps along the way. We have not yet examined all possible precursors to KSMs and APIs. Our work, to date, has not addressed over-the-counter drug products, animal drugs, compounded drugs, medical equipment and devices, or medical supplies, so we are not able to provide lists related to these areas in our response.

You asked about products that “may swiftly be in high demand and of which we may have shortages across a range of plausible public health crises.” Changes in drug demand or development of drug shortages are typically the result of specific ‘trigger events’ and pre-existing infrastructure issues in the pharmaceutical market. There are a number of plausible mechanisms by which drug shortages may be precipitated in the market. Among the types of events that may trigger unavailability of drugs in the U.S. market are: “(1) increased demand (or medical need) for a drug, (2) unavailability of raw materials, (3) lack of production capacity, (4) poor quality processes and products, (5) disruption of shipping and transport, and (6) business decisions related to corporate priorities and profit.”<sup>45</sup>

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<sup>45</sup> Schondelmeyer S, Siefert J, Margraf D, et al, COVID-19: The CIDRAP Viewpoint, Part 6: Ensuring a Resilient US Prescription Drug Supply, October 21, 2020, p. 7, available on the Resilient Drug Supply Project website at: <https://www.cidrap.umn.edu/rds> or directly at: <https://www.cidrap.umn.edu/sites/default/files/public/downloads/cidrap-covid19-viewpoint-part6.pdf>

There are a number of reasons, or root causes, which can lead to an inadequate or disrupted supply chain for a drug product. These disruptions may occur because of conditions in the business, economic, climatic, political, regulatory, and technological environments. The following scenarios are plausible causes of drug shortages, and in fact most have already occurred somewhere in the world. Potential drug supply threat scenarios include:

- “1. Climate change and natural disasters such as hurricanes, tornadoes, tsunamis, floods, infectious disease outbreaks and pandemics;
2. Human behavior in response to actual or rumored drug shortages, including responses such as panic, hoarding, or changes in trust of therapies or vaccines;
3. Human-made disasters such as fires, explosions, or nuclear disasters;
4. Unintentional contamination while synthesizing and manufacturing a drug product (e.g., nitrosamine contaminants in valsartan (2018), ranitidine (2019), and metformin (2020));
5. Intentional contamination (or terrorism) of critical acute or chronic drugs during the synthesis, production, or distribution process;
6. Business decisions and industry consolidation among drug firms;
7. Bankruptcy or other economic behavior of a major pharmaceutical firm;
8. Political or diplomatic crisis (e.g., India’s ban on export of certain drugs in 2020); and
9. Military action or war with one or more major countries, such as China, North Korea, or Iran”<sup>46</sup>

Potentially all drug products in the U.S. market could experience disruptions in their supply chain resulting in shortages and lack of availability to American patients who need them. However, it is possible to identify specific sets of drugs that are more likely to experience significantly increased demand, seriously disrupted supply, or a vulnerable and dysfunctional infrastructure. The following sets of drugs are more likely to have a significant impact on public health if they have a shortage for any reason: (1) essential and critical drugs; (2) drugs with concentrated sources of origin or shipping pathways; and (3) drugs which have previously experienced a shortage or which are similar to drugs previously in shortage.

Several types of essential and critical drug lists have been created by various groups with an interest in public health issues. First, the World Health Organization (WHO) publishes the WHO Model List of Essential Medicines. The 21<sup>st</sup> edition of the WHO list was published in 2019 and contains 461 drugs.<sup>47</sup> The essential medicines list includes drugs from a wide range of therapeutic categories to meet the most important needs of a nation’s health system. In the fall of 2019, the FDA matched 370 CDER-approved drugs in the U.S. with the drugs in the WHO Model List of Essential Medicines. FDA found that there were 1,079 facilities in the world that were making API for these 370 drugs. There were 166 (15%) API producers in China, 221 (21%) in the United States, and 687 (64%) in the rest of the World. The FDA determined that only three of these WHO essential medicines relied upon China as the sole source of API. The three medicines produced

<sup>46</sup> Schondelmeyer S, et al, Ensuring a Resilient US Prescription Drug Supply, October 21, 2020.

<sup>47</sup> World Health Organization, The selection and use of essential medicines: report of the WHO Expert Committee on Selection and Use of Essential Medicines, 2019 (including the 21st WHO Model List of Essential Medicines and the 7th WHO Model List of Essential Medicines for Children). Geneva: World Health Organization, 2019 (WHO Technical Report Series, No. 1021).

only in China were capreomycin, streptomycin, and sulfadiazine. A copy of the 21<sup>st</sup> WHO Model List of Essential Medicines is attached as Appendix A.

The FDA, in consultation with federal partners, has identified and published a List of Essential Medicines, Medical Countermeasures, Critical Inputs.<sup>48</sup> Pursuant to Executive Order 13944, the FDA developed criteria for identification of essential drug and biological products, medical countermeasures, and medical device countermeasures.<sup>49</sup> The list contains 227 drug and biological products and 96 medical device countermeasures. The FDA maintains a list of drugs that are used as medical countermeasures (MCMs), which fall into four categories of threats: biological threats, chemical threats, influenza, and radiation threats. These MCMs have been included in the FDA List of Essential Medicines, Medical Countermeasures, Critical Inputs. The FDA list itemized the critical inputs (i.e., active pharmaceutical ingredients of essential medicines and medical countermeasures and other essential ingredients or components). A copy of the FDA's list known as the Drug and Biologic Essential Medicines, Medical Countermeasures, and Critical Inputs for the List Described in Section 3(c) of the Executive Order 13944 is attached as Appendix B.

The Resilient Drug Supply Project (RDSP) at the University of Minnesota has developed a list of Critical Acute Drugs.<sup>50</sup> The RDSP defines "critical acute drugs" as "drugs that "when medically needed in acute care must be available and used within hours or days of the need or the patient will suffer serious outcomes which may include disability or death. Absence of a Critical Acute Drug, or lack of availability of an effective substitute, may cause serious health outcomes or limited ability to provide humane care." The Critical Acute Drug list was created by an expert panel convened by the University of Minnesota's RDSP on December 11 & 12, 2018. Participating experts came from government, academia, and the private sector and represented the fields of pharmacy, medicine, nursing, public health, others in clinical health care, pharmaceutical supply chains, emergency preparedness and response, emergency medical services, and drug distribution. The list contains 156 drug molecules or drug types and covers a wide variety of therapeutic categories. A copy of this list is attached to my written testimony from May 19, 2021 before the Senate Committee on Homeland Security and Government Affairs.<sup>51</sup> These 156 drug molecules account for nearly 20,000 actively marketed drug products (at the NDC level) in the U.S. market. The 156 Critical Acute Drugs were compared against the FDA and ASHP drug shortage lists to determine how many of these critical drugs were in shortage. We found that 38.5% of them (60 of 156) were in short supply as recently as the end of January 2021 according to the ASHP drug shortage list.<sup>52</sup> The US FDA, with their more stringent criteria for declaring a shortage, showed

<sup>48</sup> Stephen M. Hahn, Commissioner of Food and Drugs, U.S. FDA, FDA Publishes List of Essential Medicines, Medical Countermeasures, Critical Inputs Required by Executive Order, October 30, 2020; accessed on July 3, 2021 at: <https://www.fda.gov/news-events/press-announcements/fda-publishes-list-essential-medicines-medical-countermeasures-critical-inputs-required-executive>

<sup>49</sup> FDA, Criteria For Identifying Human Drug and Biologic Essential Medicines, Medical Countermeasures, and Critical Inputs for the List Described in Section 3(c) of the Executive Order 13944, Oct. 30, 2020. Accessed on July 3, 2021 at: <https://www.fda.gov/media/143407/download>.

<sup>50</sup> The Resilient Drug Supply Project (RDSP) is a research program of the University of Minnesota's CIDRAP and the PRIME Institute. The RDSP has been funded by a generous gift from the Walton Family Foundation.

<sup>51</sup> Schondelmeyer S, et al, Ensuring a Resilient US Prescription Drug Supply, October 21, 2020.

<sup>52</sup> ASHP. Current Drug Shortages: Drug Shortages and Management, <https://www.ashp.org/Drug-Shortages/Current-Shortages>.

24.4% (38 of 156) of the RDSP Critical Acute Drugs were in shortage at the same time.<sup>53</sup> Both of these drug shortage rates are unacceptable whether in times of a pandemic or not.

Early in January of 2020, the RDSP recognized that the coronavirus outbreak could become a major public health crisis. The staff at the RDSP created a list of Critical COVID-19 Drugs. Drugs on the list were therapeutic agents that could be “used in the active treatment of COVID-19 positive patients or their COVID-19 related symptoms.” Similar to the Critical Acute Drug list, absence of a Critical COVID-19 Drug, or lack of availability of an effective substitute, may cause serious health outcomes or limited ability to provide humane care.” This list contained 40 drug molecules or drug types in several therapeutic categories. A copy of this list is attached to my written testimony from May 19, 2021 before the Senate Committee on Homeland Security and Government Affairs.<sup>54</sup> These 40 drug molecules account for nearly 8,000 actively marketed drug products (at the NDC level) in the U.S. market. The 40 Critical COVID-19 Drugs were compared against the FDA and ASHP drug shortage lists to determine how many of these critical drugs were in shortage. We found that 70.0% of them (28 of 40) were in short supply as recently as the end of January 2021 according to the ASHP drug shortage list.<sup>55</sup> The US FDA, with their more stringent criteria for declaring a shortage, showed 40.0% (16 of 40) of the RDSP Critical COVID-19 Drugs were in shortage at the same time.<sup>56</sup> Both of these drug shortage rates are unacceptable whether in times of a pandemic or not.

Another way to identify drug products that may have vulnerabilities which could result in a swift increase in demand or a sudden shortage in the market is to look for drugs that have a heavy dependence, or even over-reliance, on foreign sources of supply, particularly when concentrated in one or two countries. The University of Minnesota’s RDSP in January of 2020 realized that the viral infections beginning to show up in China, and later in other countries, may lead to respiratory infections in COVID-19 patients including secondary bacterial infections. An evidence-based article enumerating the antibiotics most commonly useful for treating community-acquired pneumonia was reviewed and 21 specific antibiotics were identified.<sup>57</sup> All active NDCs for these 21 antibiotics in the U.S. market were identified using data from MediSpan<sup>58</sup> and from the FDA Drug Label Files.<sup>59</sup> The geographic origin of each NDC was identified from the labels in the FDA Drug Label File and other sources and the rate of foreign dependence for each antibiotic was calculated as the percent of NDCs for each antibiotic molecule from a foreign source. Nine of the 21 antibiotic molecules had 100% of their NDCs with a foreign country of origin and 19 of 21 (90.5%) antibiotic molecules had greater than 75% of NDCs from a foreign source. A more detailed analysis was done to determine the dependence on Asian sources for the NDCs of these 21 antibiotic molecules. Six of the antibiotic molecules had greater than 75% of the NDCs from Asian sources and 14 of 21 (67.7%) antibiotic molecules had greater than 50% of NDCs from

<sup>53</sup> FDA, FDA Drug Shortages, <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.

<sup>54</sup> Schondelmeyer S, et al, Ensuring a Resilient US Prescription Drug Supply, October 21, 2020.

<sup>55</sup> ASHP, Current Drug Shortages: Drug Shortages and Management, <https://www.ashp.org/Drug-Shortages/Current-Shortages>.

<sup>56</sup> FDA, FDA Drug Shortages, <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.

<sup>57</sup> Metlay J, et al, Diagnosis and Treatment of Adults with Community-acquired Pneumonia, Am J Respir Crit Care Med Vol 200, Iss 7, pp e45–e67, Oct 1, 2019.

<sup>58</sup> MediSpan, MediSpan Rx Price Pro, Wolters Kluwer, Indianapolis, IN, January 15, 2020.

<sup>59</sup> FDA, FDA Drug Label Files as of February 2, 2020 and found at: <https://dailymed.nlm.nih.gov/dailymed/spl-resources-all-drug-labels.cfm>.

Asian sources. Attached as Appendix C is a figure showing the 21 key antibiotic molecules and the share of their NDCs that are from foreign sources or Asian sources. These antibiotic molecules should be monitored to assess their continued availability and to prevent or mitigate any drug shortages that may occur.

Shipments of drug products are another way to track the movement of drugs from factories involved in the manufacturing and production process. The RDSP examined shipments recorded in the Panjiva database<sup>60</sup> to determine the share of certain drug shipments that originate in various countries. In this case, we used pre-pandemic shipment data (2019) and at least 9 drug molecules were identified that had more than 50% of their shipments to the U.S. originating in China. Seven of the 9 (77.8%) drugs predominantly from China had shortages in 2020 according to ASHP.<sup>61</sup> Ten drug molecules had greater than 50% of their shipments to the U.S. originating in Asian countries. Eight of the 10 (80%) drugs predominantly from Asian sources had shortages in 2020. Twelve drug molecules had greater than 50% of their shipments to the U.S. originating from a foreign country. Nine of the 12 (75%) drugs predominantly from foreign sources had shortages in 2020. Attached as Appendix D is a figure titled U.S. Drug Supply's Foreign Dependence Based on Shipping Data for Critical Access Drugs: 2019. These 31 critical drug molecules with over-reliance on China, or other foreign sources, should be monitored to assure a safe and resilient supply for the American market.

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<sup>60</sup> Panjiva is a service product of S&P Market Intelligence that brings “transparency to global trade through our robust global coverage, powerful machine-learning technologies, and dynamic data visualizations. Data was from calendar year 2019.

<sup>61</sup> ASHP. Current Drug Shortages: Drug Shortages and Management, <https://www.ashp.org/Drug-Shortages/Current-Shortages>.

**Appendix A**

**21st WHO Model List of Essential Medicines  
and the  
7th WHO Model List of Essential Medicines for Children  
Geneva: World Health Organization  
WHO Technical Report Series, No. 1021  
2019**

# The Selection and Use of Essential Medicines

Report of the WHO Expert Committee on Selection and Use of Essential Medicines, 2019 (including the 21st WHO Model List of Essential Medicines and the 7th WHO Model List of Essential Medicines for Children)

The World Health Organization was established in 1948 as a specialized agency of the United Nations serving as the directing and coordinating authority for international health matters and public health. One of WHO's constitutional functions is to provide objective and reliable information and advice in the field of human health, a responsibility that it fulfils in part through its extensive programme of publications.

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# The Selection and Use of Essential Medicines

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*This report contains the views of an international group of experts, and does not necessarily represent the decisions or the stated policy of the World Health Organization*



The selection and use of essential medicines: report of the WHO Expert Committee on Selection and Use of Essential Medicines, 2019 (including the 21st WHO Model List of Essential Medicines and the 7th WHO Model List of Essential Medicines for Children).

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## Annex 4

### Alphabetical list of essential medicines (with ATC classification code numbers)

Medicine or item as in EML	ATC code	Section
abacavir (ABC)	J05AF06	6.4.2.1
abacavir + lamivudine	J05AR02	6.4.2
abiraterone	L02BX03	8.2.4
acetazolamide	S01EC01	21.4
acetic acid	S02AA10	28
acetylcysteine	V03AB23	4.2
acetylsalicylic acid	B01AC06	12.5.1
acetylsalicylic acid	N02BA01	2.1; 7.1; 29.3
aciclovir	J05AB01	6.4.1
aciclovir	S01AD03	21.1
adalimumab	L04AB04	8.1
albendazole	P02CA03	6.1.1; 6.1.2
allopurinol	M04AA01	8.2.5; 29.1
alteplase	B01AD02	12.5.2
amikacin	J01GB06	6.2.1; 6.2.5
amiloride	C03DB01	16
amiodarone	C01BD01	12.2
amitriptyline	N06AA09	2.3; 24.2.1
amlodipine	C08CA01	12.3
amodiaquine	P01BA06	6.5.3.1
amoxicillin	J01CA04	6.2.1
amoxicillin and enzyme inhibitor*	J01CR02	6.2.1; 6.2.5
amphotericin B	J02AA01	6.3; 6.5.2
ampicillin	J01CA01	6.2.1
anastrozole	L02BG03	8.2.4
anti-D immunoglobulin	J06BB01	11.2.1
aprepitant	A04AD12	17.2
arsenic trioxide	L01XX27	8.2.1
artemether	P01BE02	6.5.3.1
artemether and lumefantrine	P01BF01	6.5.3.1
artemimol and piperazine	P01BF05	6.5.3.1
artesunate	P01BE03	6.5.3.1
artesunate and amodiaquine	P01BF03	6.5.3.1



Medicine or item as in EML	ATC code	Section
artesunate and mefloquine	P01BF02	6.5.3.1
artesunate and pyronaridine	P01BF06	6.5.3.1
ascorbic acid	A11GA01	27
asparaginase	L01XX02	8.2.1
atazanavir	J05AE08	6.4.2.3
atazanavir + ritonavir	J05AR23	6.4.2.3
atracurium	M03AC04	20
atropine	A03BA01	1.3; 4.2
atropine	S01FA01	21.5
azathioprine	L04AX01	8.1; 29.2
azithromycin	J01FA10	6.2.2; 21.1
bacterial and viral vaccines, combined*	J07CA	19.3
barium sulfate with suspending agents*	V08BA01	14.2
beclometasone	R03BA01	25.1
bedaquiline	J04AK05	6.2.5
bendamustine	L01AA09	8.2.1
benzathine benzylpenicillin	J01CE08	6.2.1
benznidazole	P01CA02	6.5.5.2
benzoyl peroxide	D10AE01	13.4
benzyl benzoate	P03AX01	13.5
benzylpenicillin	J01CE01	6.2.1
betamethasone	D07AC01	13.3
bevacizumab	L01XC07	21.6
bicalutamide	L02BB03	8.2.4
biperiden	N04AA02	9
bisoprolol	C07AB07	12.1; 12.2; 12.3; 12.4
bleomycin	L01DC01	8.2.1
bortezomib	L01XX32	8.2.2
budesonide	R03BA02	25.1
budesonide	R01AD05	28
budesonide and formoterol	R03AK07	25.1
bupivacaine	N01BB01	1.2
caffeine citrate	N06BC01	22.6
calcium folinate	V03AF03	8.2.1
calcium gluconate	A12AA03	4.2; 27
capecitabine	L01BC06	8.2.1
carbamazepine	N03AF01	5; 24.2.2
carbamide*	D02AE01	13.4

Annex 4: Alphabetical list of essential medicines (with ATC classification code numbers)

Medicine or item as in EML	ATC code	Section
carbetocin	H01BB03	22.3
carbimazole*	H03BB01	18.7
carbohydrates*	B05BA03	26.2
carboplatin	L01XA02	8.2.1
cefalexin	J01DB01	6.2.1
cefazolin	J01DB04	6.2.1
cefixime	J01DD08	6.2.2
cefotaxime	J01DD01	6.2.2
ceftazidime	J01DD02	6.2.2
ceftazidime and beta-lactamase inhibitor*	J01DD52	6.2.3
ceftriaxone	J01DD04	6.2.2
cefuroxime	J01DC02	6.2.2
chlorambucil	L01AA02	8.2.1
chloramphenicol	J01BA01	6.2.1
chlorhexidine	D08AC02	15.1; 22.6
chloroquine	P01BA01	6.5.3.1; 6.5.3.2; 29.2
chloroxylenol	D08AE05	15.2
chlorpromazine	N05AA01	24.1
cholera vaccines*	J07AE	19.3
ciclosporin	L04AD01	8.1
ciprofloxacin	J01MA02	6.2.2
ciprofloxacin	S02AA15	28
cisplatin	L01XA01	8.2.1
clarithromycin	J01FA09	6.2.2
clindamycin	J01FF01	6.2.1
clofazimine	J04BA01	6.2.4; 6.2.5
clomifene	G03GB02	22.2
clomipramine	N06AA04	24.4
clopidogrel	B01AC04	12.5.1
clotrimazole	G01AF02	6.3
cloxacillin	J01CF02	6.2.1
clozapine	N05AH02	24.1
coagulation factor IX, II, VII and X in combination*	B02BD01	11.2.2
coagulation factor VIII*	B02BD02	11.2.2
codeine	R05DA04	2.2
colecalfiferol	A11CC05	27
colistin	J01XB01	6.2.3
Combinations of drugs for treatment of tuberculosis*	J04AM	6.2.5

Medicine or item as in EML	ATC code	Section
cyclizine	R06AE3	2.3
cyclophosphamide	L01AA01	8.2.1
cycloserine	J04AB01	6.2.5
cytarabine	L01BC01	8.2.1
dabigatran etexilate*	B01AE07	10.2
dacarbazine	L01AX04	8.2.1
daclatasvir	J05AX14	6.4.4.2.1
dactinomycin	L01DA01	8.2.1
dapsone	J04BA02	6.2.4
darbepoetin alfa	B03XA02	10.1
darunavir	J05AE10	6.4.2.3
dasabuvir	J05AX16	6.4.4.2.2
dasatinib	L01XE06	8.2.2
daunorubicin	L01DB02	8.2.1
deferoxamine	V03AC01	4.2; 10.3
delamanid	J04AK06	6.2.5
desmopressin	H01BA02	10.2
dexamethasone	H02AB02	2.3; 3; 8.2.4; 17.2; 22.5
dextran*	B05AA05	11.3
diatrizoic acid*	V08AA01	14.2
diazepam	N05BA01	2.3; 5; 24.3
diazoxide	V03AH01	18.6
diethylcarbamazine	P02CB02	6.1.2
digoxin	C01AA05	12.2; 12.4
diloxanide	P01AC01	6.5.1
dimercaprol	V03AB09	4.2
diphtheria antitoxin	J06AA01	19.2
diphtheria toxoid*	J07AF01	19.3
docetaxel	L01CD02	8.2.1
docusate sodium	A06AA02	2.3
dolutegravir	J05AX12	6.4.2.4
dolutegravir + lamivudine + tenofovir	TBA	6.4.2
dopamine	C01CA04	12.4
doxorubicin	L01DB01	8.2.1
doxycycline	J01AA02	6.2.1; 6.5.3.1; 6.5.3.2
edetates*	V03AB03	4.2
efavirenz (EFV or EFZ)	J05AG03	6.4.2.2

Medicine or item as in EML	ATC code	Section
efavirenz + emtricitabine + tenofovir disoproxil	J05AR06	6.4.2
efavirenz + lamivudine + tenofovir disoproxil	J05AR11	6.4.2
eflornithine	P01CX03	6.5.5.1
electrolytes with carbohydrates*	B05BB02	26.2
electrolytes*	B05BB01	26.2
emtricitabine + tenofovir disoproxil	J05AR03	6.4.2
enalapril	C09AA02	12.3; 12.4
encephalitis, Japanese, inactivated, whole virus*	J07BA02	19.3
encephalitis, tick-borne, inactivated, whole virus*	J07BA01	19.3
enoxaparin	B01AB05	10.2
entecavir	J05AF10	6.4.4.1.1
ephedrine	C01CA26	1.2
epinephrine	S01EA01	21.5
epinephrine (adrenaline)	C01CA24	3; 12.2; 25.1
ergocalciferol	A11CC01	27
ergometrine	G02AB03	22.3
erlotinib	L01XE03	8.2.2
erythromycin	S01AA17	21.1
erythropoietin*	B03SA01	10.1
ethambutol	J04AK02	6.2.5
ethanol	D08AX08	15.1; 15.2
ethionamide	J04AD03	6.2.5
ethosuximide	N03AD01	5
etonogestrel	G03AC08	22.1.5
etoposide	L01CB01	8.2.1
fentanyl	N02AB03	2.2
fexinidazole	P01CA03	6.5.5.1
filgrastim	L03AA02	8.2.3
fluconazole	J02AC01	6.3
flucytosine	J02AX01	6.3
fludarabine	L01BB05	8.2.1
fludrocortisone	H02AA02	18.1
fluorescein	S01JA01	14.1
fluorouracil	L01BC02	8.2.1; 13.4
fluoxetine	N06AB03	2.3; 24.2.1
fluphenazine	N05AB02	24.1

Medicine or item as in EML	ATC code	Section
folic acid	B03BB01	10.1
fomepizole	V03AB34	4.2
fosfomycin	J01XX01	6.2.3
fresh frozen plasma*	B05AX03	11.1
furosemide	C03CA01	12.4; 16
gemcitabine	L01BC05	8.2.1
gentamicin	J01GB03	6.2.1
gentamicin	S01AA11	21.1
glecaprevir + pibrentasvir	J05AP57	6.4.4.2.1
gliclazide	A10BB09	18.5.2
glucagon	H04AA01	18.6
glucose*	B05BA03	26.2
glyceryl trinitrate	C01DA02	12.1
griseofulvin	D01BA01	6.3
haloperidol	N05AD01	2.3; 24.1
halothane	N01AB01	1.1.1
hemophilus influenzae B, purified antigen conjugated*	J07AG01	19.3
heparin*	B01AB01	10.2
hepatitis A vaccine	J07BC02	19.3
hepatitis B vaccine	J07BC01	19.3
hydralazine	C02DB02	12.3
hydrochlorothiazide	C03AA03	12.3; 12.4; 16
hydrocortisone	A07EA02	17.3
hydrocortisone	D07AA02	13.3
hydrocortisone	H02AB09	3; 8.2.4; 18.1
hydroxocobalamin	B03BA03	10.1
hydroxycarbamide	L01XX05	8.2.1; 10.3
hydroxychloroquine	P01BA02	29.2
hyoscine butylbromide*	A03BB01	2.3
hyoscine hydrobromide*	A04AD01	2.3
ibuprofen	M01AE01	2.1; 7.1; 22.6
ifosfamide	L01AA06	8.2.1
imatinib	L01XE01	8.2.2
immunoglobulins, normal human, for extravascular admin*	J06BA01	11.2.1
immunoglobulins, normal human, for intravascular admin*	J06BA02	11.2.1

Medicine or item as in EML	ATC code	Section
influenza vaccine	J07BB	19.3
insulin (human)*	A10AB01	18.5.1
insulin (human)*	A10AC01	18.5.1
Iodine therapy*	H03CA	18.7; 27
iodine*	D08AG03	6.3
iohexol	V08AB02	14.2
iotrox acid*	V08AC02	14.2
ipratropium bromide	R03BB01	25.1
irinotecan	L01XX19	8.2.1
Iron in combination with folic acid*	B03AD	10.1
Iron preparations*	B03A	10.1
isoflurane	N01AB06	1.1.1
isoniazid	J04AC01	6.2.5
isoniazid, sulfamethoxazole, trimethoprim and pyridoxine*	J04AM08	6.4.2.5
isopropanol*	D08AX05	15.2
isosorbide dinitrate	C01DA08	12.1
Isotonic solutions*	B05DA	23
itraconazole	J02AC02	6.3
ivermectin	P02CF01	6.1.1; 6.1.2; 6.6
ketamine	N01AX03	1.1.2
lactulose	A06AD11	2.3
lamivudine (3TC)	J05AF05	6.4.2.1
lamivudine + nevirapine + zidovudine	J05AR05	6.4.2
lamivudine + zidovudine (ZDV or AZT)	J05AR01	6.4.2
lamotrigine	N03AX09	5
latanoprost	S01EE01	21.4
ledipasvir + sofosbuvir	J05AX65	6.4.4.2.2
lenalidomide	L04AX04	8.2.3
leuprorelin	L02AE02	8.2.4
levamisole	P02CE01	6.1.1
levodopa and decarboxylase inhibitor*	N04BA02	9
levofloxacin	J01MA12	6.2.5
levonorgestrel	G03AC03	22.1.1; 22.1.5
levonorgestrel	G03AD01	22.1.1
levonorgestrel and ethinylestradiol	G03AA07	22.1.1
levothyroxine sodium*	H03AA01	18.7
lidocaine	C01BB01	12.2

Medicine or item as in EML	ATC code	Section
lidocaine	N01BB02	1.2
lidocaine, combinations*	N01BB52	1.2
linezolid	J01XX08	6.2.3; 6.2.5
lisinopril and amlodipine	C09BB03	12.3
lisinopril and diuretics*	C09BA03	12.3
lithium*	N05AN01	24.2.2
loperamide	A07DA03	2.3
lopinavir + ritonavir (LPV/r)*	J05AR10	6.4.2.3
loratadine	R06AX13	3
lorazepam	N05BA06	5
losartan	C09CA01	12.3; 12.4
Lung surfactants	R07AA	22.6
magnesium sulfate	B05XA05	5
mannitol	B05BC01	16
measles vaccine, live attenuated*	J07BD01	19.3
mebendazole	P02CA01	6.1.1
medicinal charcoal*	A07BA01	4.1
medroxyprogesterone and estrogen*	G03AA08	22.1.2
medroxyprogesterone*	G03AC06	18.4; 22.1.2
mefloquine	P01BC02	6.5.3.1; 6.5.3.2
meglumine antimoniate	P01CB01	6.5.2
melarsoprol	P01CD01	6.5.5.1
melphalan	L01AA03	8.2.1
meningococcal vaccines*	J07AH	19.3
mercaptopurine	L01BB02	8.2.1
meropenem	J01DH02	6.2.2; 6.2.5
meropenem + vaborbactam	J01DH52	6.2.3
mesna	V03AF01	8.2.5
metformin	A10BA02	18.5.2
methadone	N07BC02	2.2; 24.5
methotrexate	L01BA01	8.2.1; 29.2
methoxy polyethylene glycol-epoetin beta	B03AX03	10.1
methyl dopa (levorotatory)*	C02AB01	12.3
methylprednisolone	H02AB04	8.2.4
methylthioninium chloride (methylene blue)	V03AB17	4.2
metoclopramide	A03FA01	2.3; 17.2
metronidazole	J01XD01	6.2.1
metronidazole	P01AB01	6.5.1
miconazole	D01AC02	13.1

Medicine or item as in EML	ATC code	Section
midazolam	N05CD08	1.3; 2.3; 5
mifepristone	G03XB01	22.3
miltefosine	L01XX09	6.5.2
misoprostol	G02AD06	22.3
morphine	N02AA01	1.3; 2.2
moxifloxacin	J01MA14	6.2.5
multienzymes (lipase, protease, etc.)*	A09AA02	17
multiple micronutrient powders	B03AE10	27
mumps vaccine, live attenuated*	J07BE01	19.3
mupirocin	D06AX09	13.2
naloxone	V03AB15	4.2
natamycin	S01AA10	21.1
neostigmine	N07AA01	20
nevirapine (NVP)	J05AG01	6.4.2.2
niclosamide	P02DA01	6.1.1
nicotinamide	A11HA01	27
nicotine*	N07BA01	24.5
nifedipine	C08CA05	22.4
nifurtimox	P01CC01	6.5.5.1; 6.5.5.2
nilotinib	L01XE08	8.2.2
nitrofurantoin	J01XE01	6.2.1
nitroprusside*	C02DD01	12.3
nitrous oxide	N01AX13	1.1.1
nivolumab	L01XC17	8.2.3
norethisterone and ethinylestradiol	G03AA05	22.1.1
norethisterone*	G03AC01	22.1.2
nystatin	D01AA01	6.3
ofloxacin	S01AE01	21.1
ombitasvir + paritaprevir + ritonavir	J05AX66	6.4.4.2.2
omeprazole	A02BC01	17.1
ondansetron	A04AA01	2.3; 17.2
oral rehydration salt formulations*	A07CA	17.5.1; 26.1
oseltamivir	J05AH02	6.4.3
oxaliplatin	L01XA03	8.2.1
oxamniquine	P02BA02	6.1.3
oxygen	V03AN01	1.1.1; 1.4
oxytocin	H01BB02	22.3
p-aminosalicylic acid*	J04AA01	6.2.5
paclitaxel	L01CD01	8.2.1



Medicine or item as in EML	ATC code	Section
paracetamol	N02BE01	2.1; 7.1
paromomycin	A07AA06	6.5.2
pegaspargase	L01XX24	8.2.1
peginterferon alfa-2a*	L03AB11	6.4.4.2.3
peginterferon alfa-2b*	L03AB10	6.4.4.2.3
penicillamine	M01CC01	4.2; 29.2
pentamidine isethionate*	P01CX01	6.5.4; 6.5.5.1
permethrin	P03AC04	13.5
pertussis vaccine	J07AJ01	19.3
phenobarbital	N03AA02	5
phenoxymethylpenicillin	J01CE02	6.2.1
phenytoin	N03AB02	5
phytomenadione	B02BA01	10.2
pilocarpine	S01EB01	21.4
piperacillin and enzyme inhibitor*	J01CR05	6.2.2
plastic IUD with copper*	G02BA02	22.1.3
plastic IUD with progestogen*	G02BA03	22.1.3
platelet concentrates	B05A	11.1
plazomicin	TBA	6.2.3
pneumococcus, purified polysaccharides antigen*	J07AL01	19.3
podophyllotoxin*	D06BB04	13.4
poliomyelitis vaccine	J07BF	19.3
polymyxin B	J01XB02	6.2.3
potassium chloride	B05XA01	26.1; 26.2
potassium ferric hexacyanoferrate (II) ·2H <sub>2</sub> O (Prussian blue)	V03AB31	4.2
potassium permanganate	D08AX06	13.2
povidone-iodine*	D08AG02	15.1
praziquantel	P02BA01	6.1.1; 6.1.3
prednisolone	H02AB06	3; 8.2.4
prednisolone	S01BA04	21.2
primaquine	P01BA03	6.5.3.1
procaine benzylpenicillin	J01CE09	6.2.1
procarbazine	L01XB01	8.2.1
proguanil	P01BB01	6.5.3.2
propofol	N01AX10	1.1.2
propranolol	C07AA05	7.2
propylthiouracil	H03BA02	18.7
prostaglandins*	C01EA	22.6

Medicine or item as in EML	ATC code	Section
protamine*	V03AB14	10.2
pyrantel	P02CC01	6.1.1
pyrazinamide	J04AK01	6.2.5
pyridostigmine	N07AA02	20
pyridoxine	A11HA02	27
pyrimethamine	P01BD01	6.5.4
pyrimethamine, combinations*	P01BD51	6.5.3.1; 6.5.3.2
quinine	P01BC01	6.5.3.1
rabies immunoglobulin	J06BB05	11.2.1
rabies vaccine	J07BG	19.3
raltegravir	J05AX08	6.4.2.4
ranitidine	A02BA02	17.1
realgar-Indigo naturalis formula	TBA	8.2.1
red blood cells*	B05AX01	11.1
retinol	A11CA01	27
ribavirin	J05AB04	6.4.3; 6.4.4.2.3
riboflavin	A11HA04	27
rifabutin	J04AB04	6.2.5
rifampicin	J04AB02	6.2.4; 6.2.5
rifampicin and isoniazid*	J04AM02	6.2.5
rifampicin, pyrazinamide and isoniazid*	J04AM05	6.2.5
rifampicin, pyrazinamide, ethambutol and isoniazid*	J04AM06	6.2.5
rifapentine	J04AB05	6.2.5
risperidone	N05AX08	24.1
ritonavir (r)	J05AE03	6.4.2.3
rituximab	L01XC02	8.2.2
rota virus diarrhea vaccines*	J07BH	19.3
rubella vaccines	J07BJ	19.3
salbutamol	R03CC02	25.1
salicylic acid	D01AE12	13.4
selenium sulfide	D01AE13	13.1
senna glycosides*	A06AB06	2.3; 17.4
silver sulfadiazine	D06BA01	13.2
simvastatin	C10AA01	12.6
snake venom antiserum*	J06AA03	19.2
sodium bicarbonate*	B05XA02	26.2
sodium chloride	B05XA03	26.2

Medicine or item as in EML	ATC code	Section
sodium fluoride	A12CD01	27
sodium nitrite	V03AB08	4.2
sodium stibogluconate	P01CB02	6.5.2
sofosbuvir	J05AX15	6.4.4.2.1
sofosbuvir + velpatasvir	J05AX69	6.4.4.2.1
Solvents and diluting agents, incl. irrigating solutions*	V07AB	26.3
spectinomycin	J01XX04	6.2.1
spironolactone	C03DA01	12.4; 16
streptokinase	B01AD01	12.5.2
streptomycin	J01GA01	6.2.5
sulfadiazine	J01EC02	6.5.4
sulfamethoxazole + trimethoprim	J01EE01	6.2.1; 6.5.4
sulfasalazine	A07EC01	17.3; 29.2
suramin sodium	P01CX02	6.5.5.1
suxamethonium	M03AB01	20
tamoxifen	L02BA01	8.2.4
tars*	D05AA	13.4
Technical disinfectants*	V07AV	15.2
telmisartan and amlodipine	C09DB04	12.3
telmisartan and diuretics*	C09DA07	12.3
tenofovir disoproxil fumarate	J05AF07	6.4.2.1; 6.4.4.1.1
terbinafine	D01BA02	13.1
testosterone	G03BA03	18.2
tetanus immunoglobulin*	J06BB02	11.2.1
tetanus toxoid*	J07AM01	19.3
tetracaine	S01HA03	21.3
tetracycline	S01AA09	21.1
thalidomide	L04AX02	8.2.3
thiamine	A11DA01	27
thiosulfate*	V03AB06	4.2; 13.1
timolol	S01ED01	21.4
tioguanine	L01BB03	8.2.1
tiotropium	R03BB04	25.1
tranexamic acid	B02AA02	10.2; 22.5
trastuzumab	L01XC03	8.2.2
tretinoin*	L01XX14	8.2.2
triclabendazole	P02BX04	6.1.3
tropicamide	S01FA06	14.1

Medicine or item as in EML	ATC code	Section
tuberculin, purified protein derivative (PPD) - BCG*	V04CF01	19.1
tuberculosis, live attenuated*	J07AN01	19.3
typhoid vaccine	J07AP	19.3
ulipristal	G03AD02	22.1.1
vaginal ring with progestogen*	G02BB02	22.1.6
valganciclovir	J05AB14	6.4.3
valproic acid	N03AG01	5; 24.2.2
vancomycin	J01XA01	6.2.2
varicella zoster vaccines*	J07BK	19.3
vecuronium	M03AC03	20
verapamil	C08DA01	12.1; 12.2
vinblastine	L01CA01	8.2.1
vincristine	L01CA02	8.2.1
vinorelbine	L01CA04	8.2.1
voriconazole	J02AC03	6.3
warfarin	B01AA03	10.2
Water for Injection	V07AB	26.3
whole blood*	B05A	11.1
xylometazoline	R01AA07	28
yellow fever vaccines	J07BL	19.3
zidovudine (ZDV or AZT)	J05AF01	6.4.2.1
Zinc products*	D02AB	13.3
zinc sulfate	A12CB01	17.5.2
zoledronic acid	M05BA08	8.2.5

\* Medicine or item name differs slightly from the name used.

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This report presents the recommendations of the WHO Expert Committee responsible for updating the WHO Model List of Essential Medicines and WHO Model List of Essential Medicines for Children. It contains a summary of the evidence presented and the Committee's consideration, justifications and recommendations for additions, deletions and changes to medicines on the Model Lists.

Annexes to the main report include the 2019 WHO Model List of Essential Medicines (21st edition) and the 2019 WHO Model List of Essential Medicines for Children (7th edition). In addition, all medicines on the Model Lists are presented according to their Anatomical Therapeutic Chemical (ATC) classification codes.

ISBN 978 92 4 121030 0



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**Appendix B**

**FDA's Drug and Biologic Essential Medicines,  
Medical Countermeasures, and Critical Inputs for the  
List Described in Section 3(c) of the Executive Order 13944  
October 30, 2020**

Drug and Biologic Essential Medicines, Medical Countermeasures, and Critical Inputs  
for the List Described in Section 3(c) of the Executive Order 13944

\*List of drugs for critical care does not include the following: diagnostic agents and medical gases other than isoflurane for general anesthesia  
+ Additional critical inputs have been identified by FDA but have not yet been expressly identified on this list because of the need to consider how to share this additional critical input information in a manner that is consistent with applicable disclosure law while providing our federal partners with the information they need to implement their obligations under the EO

DRUG NAME*	DOSAGE FORMS	CRITICAL INPUTS	IN MCM USE ONLY
<b>Drug Category: Gastrointestinal Agents</b>			
Famotidine	oral / IV	API only	
Lactulose	liquid	API only	
Loperamide	oral	API only	
Pantoprazole	IV	API only	
<b>Drug Category: Anticonvulsants</b>			
Phenytoin	IV	API only	
Levetiracetam	oral / IV	API only	
<b>Drug Category: Antiemetics</b>			
Ondansetron	IV	API only	
<b>Drug Category: Anticoagulants / Antiplatelet</b>			
Alteplase	IV	API only	
Apixaban	oral	API only	
Aspirin	oral	API only	
Ticagrelor	oral	API only	
Enoxaparin	SQ	API, heparin, crude heparin	
Heparin	IV	API and crude heparin	
Protamine	IV	API, source proteins	
Vitamin K	IV	API only	
Andexanet alfa injection	IV	genetically modified variant of human FXa	
Argatroban	IV	API only	
<b>Drug Category: Antimetabolite</b>			
Hydroxyurea	oral	API only	
<b>Drug Category: Chemotherapeutic</b>			
Cyclophosphamide	IV	API only	
<b>Drug Category: Antihistamines</b>			
Diphenhydramine	IV	API only	
<b>Drug Category: Antihypertensives / Cardiovascular</b>			
Adenosine	IV	API only	
Atropine	IV	API only	
Amiodarone	IV	API only	
Amlodipine	oral	API only	
Diltiazem	oral / IV	API only	
Esmolol	IV	API only	
Furosemide	oral / IV	API only	
Hydrochlorothiazide	oral	API only	
Hydralazine	oral / IV	API only	
Labetalol	IV	API only	
Mannitol	IV	API only	
Metoprolol	oral / IV	API only	
Nitroglycerin	oral / IV	API only	
Nitroprusside	IV	API only	
Dobutamine	IV	API only	
Phenoxybenzamine	oral	API only	
<b>Drug Category: Anti-malarial</b>			
Artesunate	IV	API only	
<b>Drug Category: Anti-Microbial</b>			
Amikacin	IV	API only	
Amphotericin B	IV	API, +	
Ampicillin	IV	API only	
Azithromycin	IV	API only	
Cefepime	IV	API only	
Ceftazidime	IV	APis only	
Ceftazidime-Avibactam	IV	APis only	
Ceftriaxone	IV	API only	
Clindamycin	IV	API only	
Daptomycin	IV	API only	
Doxycycline	oral / IV	API only	
Fluconazole	oral / IV	API only	
Micafungin	IV	API only	
Linezolid	IV	API only	
Levofloxacin	oral / IV	API only	
Mercaptopem	IV	API only	
Metronidazole	oral / IV	API only	
Piperacillin / Tazobactam	IV	APis only	
Penicillin G	IV	API only	

DRUG NAME*	DOSAGE FORMS	CRITICAL INPUTS	IN MCM USE ONLY
Rifampin	IV	API only	
Trimethoprim/Sulfamethoxazole	oral	APIs only	
Vancomycin	oral / IV	API only	
Voriconazole	IV	API, +	
Tobramycin Ophthalmic solution 0.3%	solution / topical	API only	
<b>Drug Category: Psychiatric Agents</b>			
Haloperidol	IM	API only	
Benzotropine	oral / IV	API only	
Olanzapine	oral	API only	
<b>Drug Category: Antipyretics</b>			
Acetaminophen	oral	API only	
Ibuprofen	oral	API only	
<b>Drug Category: Analgesics</b>			
Codeine	liquid	API only	
Fentanyl	IV	API only	
Hydromorphone	oral / IV	API only	
Morphine	IV / elixir	API only	
Lidocaine/Epinephrine	solution for SQ local	APIs only	
<b>Drug Category: Antiseptics / Disinfectants</b>			
Chlorhexidine	solution / topical	API only	
Povidone-Iodine 10% Solution	solution	API only	
Topical/surface alcohol-based sanitizers	topical	API only	
<b>Drug Category: Antivirals</b>			
Acyclovir	IV	API only	
Valganciclovir	oral	API only	
Foscarnet	IV	API only	
Doxilamivir	oral / liquid	API only	
Peramivir	IV	API only	
Darunavir/cobicistat	oral	APIs only	
<b>Drug Category: Ophthalmic /Glaucoma</b>			
Timolol Maleate Ophthalmic Solution 0.5%	solution	API only	
<b>Drug Category: Pulmonary</b>			
Albuterol	MDI / NEB	NEB: API only MDI: API, critical device components, +	
Ipratropium Bromide	MDI / NEB	NEB: API only MDI: API, critical device components, +	
N-acetylcysteine	IV Solution	API only	
Surfactant	solution	API only	
<b>Drug Category: Chemotherapy / Immunosuppressants / Immunomodulators</b>			
Tacrolimus	oral	API, +	
Mycophenolate Mofetil	oral / suspension	API only	
<b>Drug Category: human granulocyte colony-stimulating factor</b>			
Filgrastim	SQ	API only	
<b>Drug Category: Anticholinergic Secretions</b>			
Glycopyrrolate	IV	API only	
<b>Drug Category: Dialysis Agents</b>			
Continuous Renal Replacement Solution	solution	API only	
<b>Drug Category: Glycemic Control</b>			
Glargine	SQ	API and master cell bank storage	
Insulin regular	IV	API and master cell bank storage	
Dextrose 50% injection	IV	API only	
<b>Drug Category: Paralytics</b>			
Cisatracurium	IV	API only	
Rocuronium	IV	API only	
Vecuronium	IV	API only	
Succinylcholine	IV	API only	
<b>Drug Category: Reversal Agents</b>			
Glucagon	IV	API only	
Flumazenil	IV	API only	
Methylene Blue	IV	API only	
Naloxone	IV	API only	
Sugammadex	IV	API only	
Esomeprazole	IV	API only	
<b>Drug Category: Sedatives / Hypnotics</b>			
Dexmedetomidine	IV	API only	
Etomidate	IV	API only	

DRUG NAME*	DOSAGE FORMS	CRITICAL INPUTS	IN MCM USE ONLY
Ketamine	IV	API only	
Lorazepam	IV	API only	
Midazolam	IV / IM	API only	
Propofol	IV	API, +	
<b>Drug Category: Anesthetic</b>			
Soflurane	gas	API only	
<b>Drug Category: Malignant Hyperthermia</b>			
Dantrolene	IV	API only	
<b>Drug Category: Steroids</b>			
Dexamethasone	IV	API only	
Hydrocortisone	oral / IV	API only	
Methylprednisolone	IV	API only	
<b>Drug Category: Endocrine</b>			
Levothyroxine	IV	API only	
Propylthiouracil	oral	API only	
Zoledronic acid	IV	API only	
Desmopressin acetate	IV	API only	
<b>Drug Category: Vaccines</b>			
Rabies Vaccine	IM	Rabies Virus Strain Flury Leo Antigen, or Virus strain PM-1503-3M Antigen	
Tetanus Vaccine	IM	Clostridium tetani toxoid antigen	
<b>Drug Category: Vasopressors</b>			
Epinephrine	IV / prefilled syringe	API, autoinjector (4 applications)	
Norepinephrine	IV	API only	
Phenylephrine	IV	API only	
Vasopressin	IV	API only	
<b>Drug Category: Volume Expanders</b>			
Dextrose 5% Water	IV	API only	
Dextrose 10% Water	IV	API only	
Lactated Ringers (LR)	IV	API only	
Sodium Chloride 0.45%	IV	API only	
Sodium Chloride 0.9%	IV	API only	
Sodium Chloride 3%	IV	API only	
<b>Drug Category: Additives</b>			
Calcium Gluconate	IV	API only	
Magnesium Sulfate	IV	API only	
Potassium Chloride	oral / IV	API only	
Sodium bicarbonate 5% injection	IV	API only	
Thiamine	IV	API only	
Cyanocobalamin 1000 mcg/ml	IM	API only	
Sodium Phosphate	IV	API only	
<b>Drug Category: Nutrition</b>			
Intralipid 20%	IV	API, +	
Trophamine (AA for infants)	IV	API only	
Zinc	IV	API only	
Cupric Chloride	IV	API only	
<b>Drug Category: Other</b>			
Octreotide	IV	API, +	
Hemin for injection	IV	Hemin from processed red blood cells	
Anticoagulants in Blood Bags and storage solutions	IV	Citrate, phosphate, dextrose, adenine	
<b>Drug Category: Blood and Blood Products</b>			
Source plasma	further mfr	Human plasma	
Transfusible Blood Components: WB, RBC, Platelets, Plasma, Cryo	IV	Human venous blood	
S/D Plasma (Octaplas)	IV	Pooled human plasma	
<b>Drug Category: Fractionated Plasma Products</b>			
Albumin	IV	Pooled human plasma	
C-1 esterase inhibitor	IV	Pooled human plasma, or milk of transgenic rabbits	
Factor VII, VIII, X, XIII products	IV	Pooled human plasma or recombinant DNA technology	
Activated Factor VII	IV	Pooled human plasma or recombinant DNA technology	
von Willebrand Factor	IV	Pooled human plasma or recombinant DNA technology	
Protein C	IV	Pooled human plasma or recombinant DNA technology	
Antithrombin	IV	Pooled human plasma or recombinant DNA technology	
Anti-inhibitor coagulant complex	IV	Pooled human plasma or recombinant DNA technology	
Fibrin sealant products	topical / intra-operative	Fibrinogen Human, Human Thrombin	
Prothrombin complex concentrate	IV	Human Source Plasma	
Fibrinogen products	IV	Human plasma-derived fibrinogen concentrate	

DRUG NAME*	DOSAGE FORMS	CRITICAL INPUTS	IN MCM USE ONLY
Thrombin products	IV	Prothrombin and thromboplastin of bovine origin; human coagulation protein produced through recombinant DNA technology; or pooled human plasma	
<b>Drug Category: Immune Globulins</b>			
Immune Globulin	IV / IM / subcutaneous	Pooled human plasma, immunoglobulin G	
<b>Drug Category: Hyperimmune Globulins</b>			
Botulism immune globulin	IV	Pooled human plasma from persons who were immunized with recombinant botulinum vaccine for serotypes A and B	
Rabies immune globulin	IV	Plasma from human donors immunized with rabies vaccine	
Tetanus immune globulin	IV	Plasma of human donors immunized with tetanus toxoid	
<b>Drug Category: Animal-Derived IG Products</b>			
Anti-thymocyte globulin products	IV	Immunoglobulin G, obtained by immunization of rabbits with human thymocytes	
Black widow spider anti-venin (Latrodectus mactans)	IV	Normal horse serum from immunized horses	
Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) Equine	IV	Purified F(ab') <sub>2</sub> plus F(ab') <sub>2</sub> -related immune globulin fragments derived from equine plasma	
Centruroides Immune Fab (scorpion)	IV	Plasma of horses immunized with venom of 4 species of scorpions	
Crotalidae Immune Fab (North American rattlesnakes)	IV	Plasma from horses immunized with venom of North American rattlesnake	
Crotalidae Polyvalent Immune Fab (rattlesnake, water moc, cottonmouth)	IV	Immune globulins obtained from healthy sheep immunized with North American snake venom (multi)	
Coral Snake Antivenom (antivenin) (Micrurus fulvius)	IV	Plasma from horses immunized with North American Coral Snake (Eastern Coral & Texas Coral Snakes)	
Digi Immune Fab (digoxin)	IV	Immune globulin fragments from blood of healthy sheep immunized with digoxin derivative	
<b>Drug Category: Unapproved Drugs Initiative</b>			
Potassium iodide - OTC for Radiation Emergency but also could be used thyroid storm	oral solution	API only	
Activated charcoal - not approved	oral		
Selenium	IV	Neonate selenium deficiency	
<b>Drug Category: Chemical Threat MCMs</b>			
Atropine Al	IM	API and Autoinjector	x
Diazepam	IM or IV	API only	x
Dual chamber atropine/pralidoxime Al - See Antidote Treatment Nerve Agent Autoinjector (ATNAA - DoD) and DuoDote (civilian)	IM	APIs and Autoinjector	x
Hydroxocobalamin	IV	API only	x
Naloxone HCl Al	IM	API and Autoinjector	x
Pralidoxime chloride & Al	IM or IV	API and Autoinjector	x
Pyridostigmine bromide	oral (30 mg)	API only	x
Sodium nitrite	IV	API only	x
Sodium thiosulfate	IV	API only	x
<b>Drug Category: Radiologic-Nuclear Threat MCMs</b>			
Calcium diethylenetriamine pentaacetate (DTPA)	IV	API only	x
Ferric Hexacyanoferrate (Prussian blue; Radiogardase)	oral	API only	x
Pegfilgrastim (Neulasta)	SQ	API, master cell bank storage, +	x
Sargramostim (Leukine)	SQ	API only	x
Zinc diethylenetriamine pentaacetate (DTPA)	IV	API only	x
Hematopoietic Progenitor Cells, Cord Blood (HPC-C)	injectable	Human Cord Blood	x
<b>Drug Category: Biological Threat MCMs</b>			
Amoxicillin	liquid / oral	API only	x
Ciprofloxacin HCl	liquid / oral	API only	x
Imipenem	IV	API only	x
Levofloxacin	liquid	API only	x
Moxifloxacin HCl	oral / IV	API only	x
Obiltoximab	IV	API only and master cell bank storage	x
Omadaacycline	oral / IV	API only	x
Raxibacumab	IV	API only and master cell bank storage	x
Tecovirimat	oral	API only	x
Adenovirus Type 4 and Type 7 Vaccine, Live, Oral	injectable	Human Adenovirus E Serotype 4 Strain CL-68578, Human Adenovirus B Serotype 7 Strain 55142 Antigens	x
Anthrax Immune Globulin Intravenous	injectable	Human plasma from donors who are immunized with Anthrax Vaccine Adsorbed	x
Anthrax Vaccine, Adsorbed	injectable	Bacillus anthracis Strain V770-NP1-R Antigens	x
Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) Equine	injectable	Plasma obtained from horses that have been immunized with specific serotype of botulinum toxoid and toxin	x

DRUG NAME*	DOSAGE FORMS	CRITICAL INPUTS	IN MCM USE ONLY
Botulism Immune Globulin	injectable	Pooled human plasma from persons who were immunized with recombinant botulinum vaccine for serotypes A and B	x
Cholera Vaccine, Live Oral	oral	Vibrio cholerae CVD 103-HGR Strain Live Antigen	x
Dengue Tetravalent Vaccine, Live	injectable	Chimeric yellow fever dengue (CYD) virus serotypes 1, 2, 3, and 4	x
Ebola Zaire Vaccine, Live	injectable	Recombinant viral vaccine consisting of a vesicular stomatitis virus (VSV) backbone deleted for the VSV envelope glycoprotein and substituted with the envelope glycoprotein of the Zaire ebolavirus (Kikwit 1995 strain)	x
Japanese Encephalitis Vaccine	injectable	Japanese Encephalitis Virus Strain SA 14-14-2 Antigen	x
Smallpox and Monkeypox Vaccine, Live, Non-Replicating	injectable	Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non-replicating orthopoxvirus	x
Plague Vaccine	injectable	Yersinia pestis organisms grown in artificial media	x
Smallpox (Vaccinia) Vaccine, Live	injectable	Vaccinia Virus Strain New York Board of Health Live Antigen	x
Typhoid VI Polysaccharide Vaccine	injectable	Salmonella Typhi TY2 W Polysaccharide Antigen	x
Typhoid Vaccine Live, Oral Ty21a	oral	Salmonella typhi TY21a Live Antigen	x
Vaccinia Immune Globulin Intravenous (Human)	injectable	Human plasma containing antibodies to vaccinia virus	x
Yellow Fever Vaccine	injectable	Yellow Fever Virus Strain 17D-204 Live Antigen	x
Imzabz	injectable	APIs only and master cell bank storage	x
<b>Drug Category: Pandemic Influenza MCMs</b>			
Baloxvir marboxil	oral	API only	x
Zanamivir	inhaled	API, Diskhaler constituent parts including body, wheel, needle level, and mouthpiece tray, base foil laminate and aluminum lid foil constituting rotadisk, +	x
Influenza A (H5N1) Monovalent Vaccine Adjuvanted	injectable	Hemagglutinin (HA) of the influenza virus strain A/Turkey/Turkey/1/2005 NIBRG-23, a reverse genetics-derived reference strain	x
Influenza A (H5N1) Virus Monovalent Vaccine Adjuvanted	injectable	Hemagglutinin (HA) of the influenza virus strain A/Indonesia/05/2005 (H5N1)	x
Influenza Virus Vaccine, H5N1	injectable	H5N1 suspension formulated to contain hemagglutinin (HA) of A/Vietnam/1203/2004 (H5N1, clade1)	x
<b>Drug Category: Burn and Blast Injuries</b>			
Bacitracin	topical	API only	x
Bacitracin / Polymyxin B	ophthalmic	API only	x
Dicyclanone HCl	oral	API only	x
Silvadene (silver sulfadiazine)	topical	API only	x
Transfusible blood and blood components	injectable	Human venous blood	x
Anticoagulants in Blood Bags and storage solutions	injectable	Citrate, Phosphate, Dextrose, Adenine	x
<b>Drug Category: COVID-19 (Material Threat Determination in place)</b>			
Tigecycline	IV	API only	x

Note: For additional information, please see the FDA web page, Executive Order 13944 List of Essential Medicines, MCMs, & Critical Inputs, at: <https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs>

Device Medical Countermeasures and Critical Inputs for the List  
Described in Section 3(c) of the Executive Order 13944

ProCode	Preferred Name	Critical Inputs
BTO	TUBE, TRACHEOSTOMY (W/NO CONNECTOR)	Connectors, valves, balloon cuffs
BTR	TUBE, TRACHEAL (W/NO CONNECTOR)	Connectors, valves, balloon cuffs
CAW	GENERATOR, OXYGEN, PORTABLE	molecular sieve, oxygen sensor, pressure chamber, pneumatic valves, mechanical
DOA	OXIMETER	red and infrared LEDs, photodetector
JOH	TUBE TRACHEOSTOMY AND TUBE CUFF	None
EOQ	BRONCHOSCOPE (FLEXIBLE OR RIGID)	optics (e.g., camera)
KTI	BRONCHOSCOPE ACCESSORY	None
BTM	VENTILATOR, EMERGENCY, MANUAL (RESUSCITATOR)	Mechanical bellows, gas filters (particulate/viral/bacterial), connectors for gas pathway,
BZE	HEATER, BREATHING SYSTEM W/MO CONTROLLER (NOT HUMIDIFIER OR NEBULIZER)	None
RLS	APNEA MONITOR	sensor
BZH	PEAK FLOW METER	flow sensor
CBK	VENTILATOR, CONTINUOUS, FACILITY USE	sensors (flow, pressure, volume), expiratory pressure regulator, BZE
BYS	OXYGENATOR, LONG TERM SUPPORT GREATER THAN 6 HOURS	oxygenator fiber
MHX	MONITOR, PHYSIOLOGICAL, PATIENT (WITH ARRHYTHMIA DETECTION OR ALARMS)	ECG electrodes/leads, SpO2 sensors, Blood pressure cuff/pump and tubing,
FZS	DUAL LUMEN ECOMO CANNULA	None
QUIZ	EXTRACORPOREAL SYSTEM FOR LONG-TERM RESPIRATORY / CARDIOPULMONARY FAILURE	pump impeller, oxygenator fiber
RIL	SYSTEM, DIALYSATE DELIVERY, SINGLE PASS	FD FXJ FLA KDI KOC KPO MPB MSY NGJ
RIZ	METER, CONDUCTIVITY, NON-REMOTE	conductivity sensor
FID	DETECTOR, LEAK, BLOOD	leak sensors
FJF	DETECTOR, AIR BUBBLE	air sensors
FJI	DIALYZER, CAPILLARY, HOLLOW FIBER	dialyzer membrane
FJK	SET, TUBING, BLOOD, WITH AND WITHOUT ANTI-REGURGITATION VALVE	None
FKB	CONNECTOR, BLOOD TUBING, INFUSION T	None
FKP	SYSTEM, DIALYSATE DELIVERY, SINGLE PATIENT	FD FXJ FLA KDI KOC KPO MPB MSY NGJ
KDI	DIALYZER, HIGH PERMEABILITY WITH OR WITHOUT SEALED DIALYSATE SYSTEM	FD FXJ FLA KDI KOC KPO MPB MSY NGJ
KDL	SET, PERFUSION, KIDNEY, DISPOSABLE	None
MOS	SYSTEM, HEMODIALYSIS, ACCESS RECIRCULATION MONITORING	FD FXJ FLA KDI KOC KPO MPB MSY NGJ
MSE	HEMODIALYZER, RE-USE, LOW FLUX	dialyzer membrane
MSF	HEMODIALYZER, RE-USE, HIGH FLUX	dialyzer membrane
PSX	CHLORINE METER	chlorine sensor
FMF	SYRINGE, PISTON	None
FMI	NEEDLE, HYPODERMIC, SINGLE LUMEN	None
FRN	PUMP, INFUSION	pumping mechanism, accessories under MRZ (anti free flow detector, pressure sensor, air-in-line detector), FPB
MEA	PUMP, INFUSION, PCA	None
MRZ	ACCESSORIES, PUMP, INFUSION	pumping mechanism, accessories under MRZ (anti free flow detector, pressure sensor, air-in-line detector), FPB
RLI	THERMOMETER, ELECTRONIC, CLINICAL	temperature sensor
FMG	STOPCOCK, I.V. SET	None
FOZ	CATHETER, INTRAVASCULAR, THERAPEUTIC, SHORT-TERM LESS THAN 30 DAYS	None
PPA	SET, ADMINISTRATION, INTRAVASCULAR	None
FPB	FILTER, INFUSION LINE	Filter
FPK	TUBING, FLUID DELIVERY	None
KPE	CONTAINER, I.V.	None
PND	MIDLINE CATHETER	None
PWH	ADMINISTRATIONS SETS WITH NEURAXIAL CONNECTORS	None
PYR	NEURAXIAL ADMINISTRATION SET - INTRATHECAL DELIVERY	None
KXG	APPLICATOR, ABSORBENT TIPPED, STERILE (swabs, general hospital)	None
FYE	DRESS, SURGICAL	None
PFY	CAP, SURGICAL	None
FXO	SUIT, SURGICAL	None
FXP	COVER, SHOE, OPERATING-ROOM	None
FYA	GOWN, SURGICAL	None
FRF	MEDICAL RECIRCULATING AIR CLEANER	Filteration media
CAH	FILTER, BACTERIAL, BREATHING-CIRCUIT	Filteration media
FMC	PATIENT EXAMINATION GLOVE	None
FME	GOWN, EXAMINATION	None
DXK	MASK, SURGICAL	None
FXV	HOOD, SURGICAL	None
FXZ	HELMET, SURGICAL	None
FYB	GOWN, PATIENT	None
FYC	GOWN, ISOLATION, SURGICAL	None
KGO	SURGEON'S GLOVES	None
LGM	CHAMBER, PATIENT ISOLATION	Air filter, air supply blower
LGN	CHAMBER, PATIENT TRANSPORT ISOLATION	Air filter, air supply blower
LJU	ACCESSORY, SURGICAL APPAREL	None
LZY	LATEX PATIENT EXAMINATION GLOVE	None
LYZ	VINYL PATIENT EXAMINATION GLOVE	None
LZA	POLYMER PATIENT EXAMINATION GLOVE	None
MSH	RESPIRATOR, SURGICAL	Filteration medium
OIG	POWDER-FREE GUAYLE RUBBER EXAMINATION GLOVE	None
OPA	POWDER-FREE NON-NATURAL RUBBER LATEX SURGEON'S GLOVES	None
OPC	POWDER-FREE POLYCHLOROPRENE PATIENT EXAMINATION GLOVE	None
OPH	RADIATION ATTENUATING MEDICAL GLOVE	None
OKZ	PEDIATRIC/CHILD FACEMASK	None
NZW	VASCULAR ACCESS FLUSH, HEPARIN	None

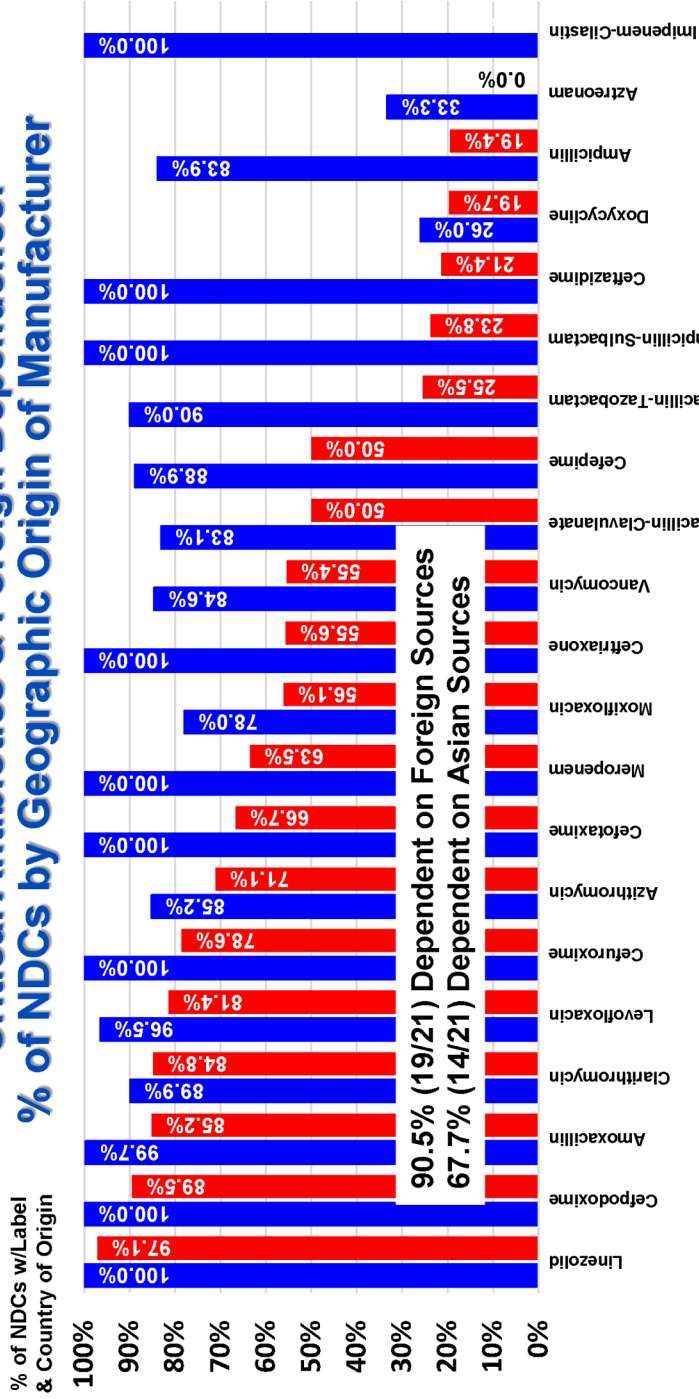
ProCode	Preferred Name	Critical Inputs
NGT	VASCULAR ACCESS FLUSH, SALINE	None
MGR	DRESSING, WOUND AND BURN, INTERACTIVE	None
GEA	NON-SURGICAL ISOLATION GOWN	None
NGR	SEALANT, DURAL	None
JJH	CLINICAL SAMPLE CONCENTRATOR	None
IKA	TUBES, WALLS, SYSTEMS, SERUM SEPARATORS, BLOOD COLLECTION	None
ISM	CULTURE MEDIA, NON-PROPAGATING TRANSPORT	None
KDT	CONTAINER, SPECIMEN MAILER AND STORAGE, STERILE	None
QEP	INFLUENZA A VIRUS SUBTYPE DIFFERENTIATION NUCLEIC ACID ASSAY	DNA primers, DNA probes, polymerase
OTG	NON-SARS CORONAVIRUS MULTIPLEX NUCLEIC ACID ASSAY	DNA primers, DNA probes, polymerase, KDW, KST, LXG
QZE	INFLUENZA A AND INFLUENZA B MULTIPLEX NUCLEIC ACID ASSAY	DNA primers, DNA probes, polymerase
PFT	REAGENTS FOR MOLECULAR DIAGNOSTIC TEST SYSTEMS	None
PRA	VIRUS NUCLEIC ACID-BASED DETECTION ASSAY	DNA primers, DNA probes, polymerase
PPM	GENERAL PURPOSE REAGENT	None
PSZ	DEVICES DETECTING INFLUENZA A, B, AND C VIRUS ANTIGENS	cartridges
QBD	MICROBIAL NUCLEIC ACID STORAGE AND STABILIZATION DEVICE	None
QDS	MERS COV AND COMMON RESPIRATORY PATHOGENS SEMI-QUANTITATIVE AND QUANTITATIVE MULTIPLEX NUCLEIC ACID DETECTION SYSTEM	DNA primers, DNA probes, polymerase
QID	DEVICE TO DETECT ANTIGENS OF BIOTHRREAT MICROBIAL AGENTS IN HUMAN CLINICAL SPECIMENS	Cartridges, nitrocellulose membrane
QIF	DEVICE TO DETECT AND IDENTIFY BIOTHRREAT MICROBIAL AGENTS IN HUMAN CLINICAL SPECIMENS	DNA primers, DNA probes, polymerase
QOI	REAL TIME NUCLEIC ACID AMPLIFICATION SYSTEM	General purpose equipment (LXG)
LIO	DEVICE, SPECIMEN COLLECTION	None
QCC	RESPIRATORY VIRUS PANEL NUCLEIC ACID ASSAY SYSTEM	DNA primers, DNA probes, polymerase

Note: For additional information, please see the FDA web page, Executive Order 13944 List of Essential Medicines, MCMs, & Critical Inputs, at: <https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs>

**Appendix C**

**Critical Antibiotics & Foreign Dependence:  
% of NDCs by Geographic Origin of Manufacturer  
February 2, 2020**

## Critical Antibiotics & Foreign Dependence: % of NDCs by Geographic Origin of Manufacturer



■ Foreign Dependence (Production outside of the U.S.)  
■ Asian Dependence (Production in China, India, Taiwan, South Korea, Bangladesh and other Asian countries.)  
Source: Antibiotics identified in Metlay J. et al. Diagnosis and Treatment of Adults with Community-acquired Pneumonia. Am J Respir Crit Care Med Vol 200, Iss 7, pp e45-e67, Oct 1, 2019. The Geographic origin of drug products at the NDC level were identified by extracting data from the FDA Drug Label Files as of February 2, 2020 and found at <https://dailymed.nlm.nih.gov/dailymed/spi-resources-all-drug-labels.cfm>.

**Appendix D**

**U.S. Drug Supply's Foreign Dependence  
Based on Shipping Data for Critical Access Drugs: 2019**

## U.S. Drug Supply's Foreign Dependence Based on Shipping Data for Critical Access Drugs: 2019

	China	Asia	Any Foreign
	<b>Critical Access Drugs with &gt;50% from China:</b>	<b>Critical Access Drugs with &gt;50% from Asia:</b>	<b>Critical Access Drugs with &gt;50% Foreign Source:</b>
	Hydrocortisone Doxycycline Acetaminophen Potassium Phenyletoin Fosphenytoin Epinephrine Sodium Phosphate Succinylcholine	Hydralazine Meropenem Dexamethasone Betamethasone Methylprednisolone Furosemide Torsemide Enoxaparin Heparin Mycophenolate	Azithromycin Lorazepam Midazolam Propofol Prednisone Warfarin Fentanyl Diphenhydramine Ampicillin Gentamicin Penicillin Insulin
<b>% of Drugs With Shortage in 2020</b>	<b>77.8%</b>	<b>80.0%</b>	<b>75.0%</b>

Source: Data is Average Annual % of Shipments to the US for Critical Drugs by Country of Origin from Panjiva (Shipments) Data for 2019.

Post-Hearing Questions for the Record  
Submitted to Kimberly Glas  
From Chairman Gary C. Peters

COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps  
Wednesday, May 19, 2021

1. In 2019, U.S. imports from China accounted for over half of personal protective equipment, including N-95 respirators, and almost half of medical protective clothing. How did the U.S. supply chain get to this point and what consequences did this overreliance have as the pandemic unfolded?

Thank you for your question, Senator Peters.

Years of offshoring this industry have had severe ramifications, as borne out by the COVID-19 pandemic, which exposed fragility in global supply chains and our nation's overreliance on Chinese raw material and finished product PPE production chains.

U.S. textile manufacturers compete in one of the most unbalanced economic playing fields of any industrial manufacturing segment, as I mentioned in my testimony.

The National Council of Textile Organizations, representing the full spectrum of U.S. textile producers, has long called for a review of U.S. trade policy and the negative ramifications for the U.S. industrial base that stem from the aggressive, predatory practices of many of our foreign competitors and the lack of reciprocal market access for our products abroad.

A confluence of major economic developments and various U.S. policy initiatives drove the massive expansion of foreign import penetration into the U.S. textile and apparel market, beginning in the late 1990s and extending through the 2008 recession and beyond.

Among the key U.S. policy decisions that greatly exacerbated the contraction of U.S. textile and apparel manufacturing during that time period were: the 1995 WTO Multi-Fiber Arrangement—Textile Quota Phase-outs began; China's accession to the WTO in 2001; and granting temporary normal trade relations with Vietnam in December 2001.

The U.S. textile industry has since stabilized and made a significant recovery in terms of overall output and exports. However, the industry continues to be undermined by our competitors in the global trade and apparel supply chain, namely by Asian countries, of which China is by far the dominant apparel exporter. These countries employ a wide range of unfair trade practices, including but not limited to: exploitative labor practices, government-subsidized production, state-owned enterprises, currency manipulation, intellectual property theft, and lax or non-existent environmental standards.

As the pandemic unfolded, our country ran into massive shortages of PPE, which was a direct function of decades of mismanaged trade policy that did not place an adequate value on U.S. manufacturing. Few

were concerned when the virtual entirety of the U.S. PPE supply chain was allowed to move offshore and global production of PPE was concentrated inside of China.

The irrational nature of U.S. trade policy combined with a lack of focused public policy to bolster this essential manufacturing in the U.S., directly jeopardized the health and safety of our healthcare workers when global supply chains broke down.

China's sheer dominance in the marketplace for these essential items further exacerbated the crisis when they chose to place export controls on PPE and raw materials as global demand surged, leading to shocking headlines revealing nurses wearing garbage bags and reusing or forgoing N95 masks.

As the United States faced devastating PPE shortages last spring, our industry received pleas from the highest levels of government to nurses and doctors on the front lines, asking for immediate assistance. The U.S. textile industry was honored to step forward and answer America's call during this time of national emergency. U.S. textile manufacturers quickly mobilized to find innovative solutions to the crisis, proactively retooling production lines and retraining workers, to eventually provide over 1 billion urgently needed items, including face masks, isolation gowns, testing swabs, and their textile components, at a time when global supply failed to meet the needs this crisis required.

However, despite all their PPE production efforts, many U.S. textile companies were confronted with idle capacity, rampant cancellation of orders, plant closures, and workers being furloughed at the height of the pandemic. Orders for the military also declined because of COVID restrictions.

Now that PPE orders in the public and private sectors have largely subsided, China is re-exerting its dominance in the marketplace.

According to PPE trade data now being tracked and reported by the Department of Commerce Office of Textiles & Apparel (OTEXA), U.S. imports of PPE grew from \$4.8 billion in 2019 to \$20.4 billion in 2020, an increase of 325 percent. Imports from China specifically jumped from \$1.6 to \$13.7 billion, up 756 percent to capture a two-thirds share of the U.S. PPE import market in 2020.

As a result, textile companies are sitting with idle equipment purchased during the pandemic while struggling with legitimate concerns over the long-term viability of producing PPE in the United States.

Other companies are wondering what the future holds for production moving into next year and the years to come. Despite all the efforts that have been taken to re-establish domestic PPE production since the start of the pandemic, unless a number of critical policy solutions are advanced now it is clear that China will cement and expand its global dominance in the marketplace for these products for decades to come.

2. Based on your experiences, did domestic manufacturers receive clear direction and support from the federal government on what was needed so they could quickly ramp up production? If not, please explain what happened and discuss any lessons learned.

It is important to note that, in a pandemic unlike anything experienced before in our lifetimes, even a fine-tuned federal procurement process may have challenges as we saw when the U.S. government attempted to respond to crises on multiple fronts.

In March 2020, we began receiving urgent requests from domestic manufacturers, the federal government, members of Congress, state and local officials, and healthcare providers from across the country who were all looking for ways to solve this country's severe PPE shortage. NCTO played a key role as a conduit in identifying domestic sources for PPE materials and potential suppliers of these lifesaving products.

We worked tirelessly to facilitate the connections and conversations necessary to form integrated supply chains, and deliver high quality, U.S.-made PPE and critical medical products to our frontline healthcare professionals and to the U.S. government.

We also engaged extensively with multiple agencies across the federal government, including the COVID response team, serving as the key industry contact point throughout the crisis.

While it is hard to predict the magnitude and severity of any multi-faceted crisis, it was apparent that the United States lacked a comprehensive strategic plan and prioritization for this critical industrial base.

This is a lesson learned and should continue to be addressed moving forward before we face the next healthcare emergency.

The varying federal government processes and the lack of long-term federal contracts also compounded the problems.

During the pandemic, there were multiple agencies making substantial PPE purchases with several fits and starts to the contracting process that created confusion and lost revenue across the industry.

HHS, FEMA, and DoD all made significant purchases of PPE during this time and there were key changes at the agencies that were acquiring PPE for the Strategic National Stockpile (SNS).

But at the at the height of the emergency, there were many conflicting demand signals that the U.S. textile industry had to navigate to supply the U.S. government timely, quality PPE.

As an example, federal contracting responsibility for an early solicitation from FEMA on behalf of HHS for the SNS was transferred to DoD, which created confusion on the part of U.S. manufacturers actively bidding on government PPE contracts.

It was apparent to our industry early on that there was a lack of necessary coordination between HHS and Defense Logistics Agency (DLA) on specific procurement priorities and miscommunication between the agencies on the PPE required.

Additionally, the U.S. government created unnecessary uncertainty through a refusal to issue long-term federal contracts for these products. Instead, virtually all federal PPE contracts during the pandemic have been restricted to short-term durations, averaging just 90-120 days. The Canadian government, by contrast, issued 10-year contracts to 2 separate N95 mask producers to foster investments in needed domestic capacity. The short-term approach on the part of our government has had a chilling effect on U.S. investment as domestic textile manufacturers are reluctant to shoulder additional risks while simultaneously struggling with a historic downturn in traditional business resulting from COVID-19.

Our industry wants to make significant investments in advanced manufacturing, like automated equipment to produce PPE, but manufacturers need longer-term, 3-to-5-year contracts to justify that investment.

To justify this investment and to avoid a repeat of the disastrous shortages we experienced at the height of this pandemic, there are a number of high-level policy priorities that should be the focus of Congress and the administration.

They include:

- A commitment to issue long-term federal government contracts to U.S. manufacturers of PPE
- The establishment of a U.S. domestic purchasing requirements for PPE with Berry-like contracting rules
- A plan to strategically deploy the Defense Production Act to expand and enhance domestic PPE production
- The need to create incentives for the private purchase of domestically made PPE by hospitals and nursing homes.

Without legislation and administration initiatives to address these obstacles to U.S. manufacturing investment in PPE, we will remain severely vulnerable and dependent on Chinese dominated supply chains for decades to come.

It is also essential moving forward that the administration and Congress have regular and clear communication with industry on the status of our industrial base, federal demand needs for PPE, and further policy tools that are necessary to foster onshoring critical manufacturing.

**Post-Hearing Questions for the Record  
Submitted to Kimberly Glas  
From Senator Jon Ossoff**

**COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps  
Wednesday, May 19, 2021**

**QUESTION:**

Please submit for the record an itemized list of the medical equipment, products, precursors for production of key medical supplies and products, and the pharmaceutical products that may swiftly be in high demand and of which we may have shortages across a range of plausible public health crises so that this committee can refer to such list as we consider other supply chains that may require reinforcement.

**RESPONSE:**

Thank you for your question, Senator Ossoff.

As mentioned in my testimony, years of offshoring this industry have had severe ramifications, as borne out during the COVID-19 pandemic, which exposed a woeful lack of existing domestic production of personal protection equipment (PPE), fragility in global supply chains and our nation's overreliance on imported Chinese raw material and finished PPE.

The National Council of Textile Organizations, representing the full spectrum of U.S. textile producers, has long called for a review of U.S. trade policy and the negative impact that predatory trading practices by foreign competitors have had on the U.S. industrial base. The damage sustained to our manufacturing capacity is a matter of national health preparedness and security and led to a devastating lack of access to critical medical supplies during the COVID-19 response.

Populating a list of all possible products and their precursors that may be in high demand in a future crisis is a tall order. Textile-based personal protective equipment (PPE) alone encompasses a diverse product grouping (gloves, gowns, masks, caps, etc.), and these products can be made of a variety of constituent materials (nonwoven material, knit fabric, woven fabrics, coated fabrics, paper, etc.). Then, there are many additional healthcare and disaster response-related products that could be subject to high demand and shortages depending on the nature of the future crisis.

In the early days of the pandemic, NCTO joined with other trade associations in developing and conducting an industry survey to identify suppliers of medical protective equipment and their component parts. This survey was used to respond to requests for emergency supplies after the onset of COVID-19 from the highest levels of the White House, the administration, and on Capitol Hill to aid in combatting the pandemic, and our database of responses is available on our website at [COVID-19 Response Textile-related Supply & PPE Database](#). The products identified are summarized below. Please note, however, that this is not an exhaustive list.

**FINISHED GOODS**

- Antimicrobial disposable wipes
- Lab coats
- Sterile packaging/Sterilization wrap
- Blood pressure cuffs
- Lateral air transfer mattress
- Surgical drapes
- Body bags/transport bags (ill or deceased)
- Face masks
- Surgical and isolation gowns
- Cots
- Medical bandages
- Surgical sponges
- Cotton swabs
- Medical beds
- Temporary shelters
- Disposable Personal Protective Apparel
- Medical equipment bags
- Textile components of heart monitoring devices
- HAZMAT suits/durable protective apparel
- Medical gauze
- Towels
- Head Covers
- Patient lifting systems (slings)
- Triage/medical tents
- Healthcare-related filtration materials
- Patient restraint/safety straps
- Hospital bed sheets/pillowcases
- Scrub suits
- Hospital privacy curtains
- Shoe covers

**INPUTS**

- Natural and man-made fibers
- Natural and man-made fiber yarns
- Fabrics and nonwoven materials
- Elastics
- Specialized chemicals/finishes
- Manufacturing equipment

In terms of additional resources, I would note that the U.S. International Trade Commission has conducted a [series of reports](#) aimed at identifying goods related to the COVID-19 response and assessing supply chain challenges and constraints. Another [list](#) was released by the FDA in relation to the August 6, 2020 Executive Order on Essential Medicines, Countermeasures, and Critical Inputs. And various legislative proposals include supply chain mapping directives and/or procurement reforms, as detailed in my testimony, aimed at continuing the work of developing a list of critical products and bolstering their supply chains.

The U.S. textile industry stands ready and able to develop and expand production capacity of these items and their inputs. Our industry wants to make significant investments in advanced manufacturing, like automated equipment to produce PPE, but manufacturers need longer-term, 3-to-5-year contracts to justify that investment.

To incentivize this investment and to avoid a repeat of the disastrous shortages we experienced at the height of this pandemic, I would like to reiterate that there are a number of high-level policy priorities that should be the focus of Congress and the administration.

They include:

- A commitment to issue long-term federal government contracts to U.S. manufacturers of PPE
- The establishment of a U.S. domestic purchasing requirements for PPE with Berry-like contracting rules
- A plan to strategically deploy the Defense Production Act to expand and enhance domestic PPE production
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Without legislation and administration initiatives to address these obstacles to U.S. manufacturing investment in PPE, we will remain severely vulnerable and dependent on Chinese dominated supply chains for decades to come.

It is also essential moving forward that the administration and Congress have regular and clear communication with industry on the status of our industrial base, federal demand needs for PPE, and further policy tools that are necessary to foster onshoring critical manufacturing.