

**PART 2: PROTECTING THE RELIABILITY
OF THE U.S. MEDICAL SUPPLY CHAIN
DURING THE COVID-19 PANDEMIC**

HEARING

BEFORE THE

**COMMITTEE ON FINANCE
UNITED STATES SENATE**

ONE HUNDRED SIXTEENTH CONGRESS

SECOND SESSION

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JULY 30, 2020
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Printed for the use of the Committee on Finance

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U.S. GOVERNMENT PUBLISHING OFFICE

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CONTENTS

OPENING STATEMENTS

	Page
Grassley, Hon. Chuck, a U.S. Senator from Iowa, chairman, Committee on Finance	1
Wyden, Hon. Ron, a U.S. Senator from Oregon	3

WITNESSES

Denning, Cathy, R.N., MSN, group senior vice president, Sourcing Operations, Analytics, and Center of Excellence, Vizient, Irving, TX	6
Wiehe, Robert J., senior vice president and chief supply chain and logistics officer, UC Health, Cincinnati, OH	8
Johnson, Charles, president, International Safety Equipment Association, Arlington, VA	10
Grant, Ernest, Ph.D., R.N., FAAN, president, American Nurses Association, Silver Spring, MD	12

ALPHABETICAL LISTING AND APPENDIX MATERIAL

Denning, Cathy, R.N., MSN:	
Testimony	6
Prepared statement with attachment	39
Responses to questions from committee members	52
Grant, Ernest, Ph.D., R.N., FAAN:	
Testimony	12
Prepared statement with attachments	57
Responses to questions from committee members	65
Grassley, Hon. Chuck:	
Opening statement	1
Prepared statement	70
Johnson, Charles:	
Testimony	10
Prepared statement with attachments	71
Responses to questions from committee members	81
Wiehe, Robert J.:	
Testimony	8
Prepared statement	85
Wyden, Hon. Ron:	
Opening statement	3
Prepared statement with attachments	92

COMMUNICATIONS

Center for Fiscal Equity	105
Healthcare Leadership Council	108
National Association of Manufacturers	112
Premier Inc.	129
City of York Healthcare Authority	134

**PART 2: PROTECTING THE RELIABILITY
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DURING THE COVID-19 PANDEMIC**

THURSDAY, JULY 30, 2020

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 9:32 a.m., in Room SD-215, Dirksen Senate Office Building, Hon. Chuck Grassley (chairman of the committee) presiding.

Present: Senators Crapo, Thune, Portman, Toomey, Cassidy, Lankford, Wyden, Carper, Cardin, Brown, Bennet, Casey, Warner, Whitehouse, Hassan, and Cortez Masto.

Also present: Republican staff: Daniel Boatright, Investigative Counsel; Caitlin Soto, Oversight Counsel; and Jeffrey Wrase, Deputy Staff Director and Chief Economist. Democratic staff: David Berick, Chief Investigator; Peter Gartrell, Investigator; and Joshua Sheinkman, Staff Director.

**OPENING STATEMENT OF HON. CHUCK GRASSLEY, A U.S.
SENATOR FROM IOWA, CHAIRMAN, COMMITTEE ON FINANCE**

The CHAIRMAN. Before I read a short opening statement, I want to explain that Senator Cassidy is going to—is it Senator Cassidy? Oh, Senator Roberts is going to take over while I do two things: one, go over and open the Senate up; and secondly, I have to be in Judiciary because we have some things where we have to have a majority to get things done.

So I do not know to what extent I am going to be face to face with you folks, but usually I would have gotten here 5 minutes early, and I would have come down and looked you in the eye and said “thank you” for participating.

I want to welcome everyone to Part 2 of the committee’s hearing on “Protecting the Reliability of the U.S. Medical Supply Chain During the COVID-19 Pandemic.” This is the second hearing to discuss COVID-19’s effect on our Nation’s medical supply chain.

Two days ago, we heard from the Department of Homeland Security’s Office of Procurement, U.S. Customs and Border Protection, and the U.S. Immigration and Customs Enforcement’s Homeland Security Investigations on their efforts to shore up the integrity of our supply chain.

Today we are going to hear from a panel of industry experts who represent all corners—maybe I should say various corners, but maybe you actually do represent all corners of the supply chain.

These witnesses have an insider's perspective and will be able to tell us about the challenges that our Nation's health-care industry is facing right now. And we will also hear how the Federal Government is collaborating and communicating with its industry partners during the pandemic.

Indeed, during our first hearing we heard that DHS is engaged in a whole-of-government response to combat the virus and is working with State, Federal, local, tribal, and international partners in a unified effort to ensure the integrity of our Nation's supply chain. Example: we heard from Homeland Security Investigations on their efforts to prevent and investigate criminal activity surrounding the pandemic, and how—it is unbelievable—they have seized hundreds of fake and faulty items of personal protective equipment, and they returned over \$17 million to victims of COVID-19 fraud.

We also heard from the Department's Chief Procurement Officer on their efforts to cut bureaucratic red tape so that FEMA could easily procure larger volumes of emergency services and supplies. These are things that front-line workers desperately need, and the Department answered the call by working with industry to review and vet companies offering COVID-19 solutions to the Federal Government.

I want to highlight that this continues to be an incredible challenge, as thousands of really unscrupulous sellers claim to be able to produce safe and legitimate supplies when what they are actually selling is fake and faulty.

Lastly, we heard from Customs and Border Protection on their efforts to speed up the delivery of high-demand personal protective equipment from manufacturers overseas. As a result of this agency's efforts, we have had over 1.3 billion pieces of personal protective equipment enter swiftly into the United States.

The list can go on and on, with many of these efforts being initiated at the beginning of the virus's foothold in the United States. However, my colleagues on the left are not telling the public these success stories. They would rather spread doom and gloom, a narrative for purposes of, I suppose, winning elections. It is a fact that the Federal Government's approach to emergency preparedness has always been fraught with challenges, and this goes back to prior administrations—and that word is plural—and beyond.

However, my Democratic colleagues would make you believe that these problems are just specific with this administration. So it is simply not true, and we have several witnesses before us today who will testify to the very fact which I will state simply here and now. The Federal Government has never been prepared to address a national emergency of this type or this scale—period.

In closing, I want to thank the witnesses present today, and all the medical and professional and first responders who work day after day to keep Americans safe and healthy. Your dedication to your community is essential to the days and weeks ahead.

Before Senator Wyden speaks as ranking member, I want to thank Senator Roberts and any other Senator who helps us out with this very difficult Thursday that I have, being three different places now. Thank you very much.

[The prepared statement of Chairman Grassley appears in the appendix.]

The CHAIRMAN. Senator Wyden, take over.

**OPENING STATEMENT OF HON. RON WYDEN,
A U.S. SENATOR FROM OREGON**

Senator WYDEN. Thank you very much, Mr. Chairman. And—

The CHAIRMAN. Senator Wyden, are you there?

Senator WYDEN. I am right here, Mr. Chairman. Can you hear me?

The CHAIRMAN. We need to turn up your volume.

Senator WYDEN. Okay.

The CHAIRMAN. You have volume now. Go ahead. And, Senator Wyden, I am sorry I am not going to be able to hear your testimony.

Senator WYDEN. Thank you, Mr. Chairman. Thank you for your courtesy.

The Finance Committee, as the chairman indicated, is focusing this week on issues dealing with the lack of high-quality PPE and other equipment during the pandemic. Now the chairman has made the focus China, and China, and China some more. And I want to be clear. I agree that counterfeiting is a problem.

What I also want to point out is, if you are focused entirely on that aspect of the issue, you skip right past something that is much bigger, which is the Trump administration's casual disinterest in leadership when it comes to getting PPE and making sure that our health-care heroes are equipped. And it goes back quite some ways.

Now the chairman said that Democrats just are spreading doom and gloom here. So what I am going to do, just for a few minutes this morning, is to spread some facts, some facts that are not in dispute.

In 2019, the Federal Government conducted a pandemic war game called "Crimson Contagion." In it, a hypothetical airborne virus originated in China made its way to the United States, infecting 110 million people and killing nearly 600,000.

The exercise concluded that the United States would need 3.5 billion N95 masks to fight a large-scale pandemic. The Trump administration took no action to acquire them. The coronavirus arrived just months later.

On March 19, 2020, with the cases beginning to go skyward, the President said the following when asked about buying and distributing PPE, and I quote: "The Federal Government is not supposed to be out there buying vast amounts of items and then shipping. Governors are supposed to be doing it," unquote.

On March 29th, Donald Trump said nurses and doctors—he actually said this—were stealing PPE. He said, and I quote, "Something is going on. You ought to look into it, as reported. Where are the masks going? Are they going out the back door?"

In mid-April, Donald Trump called reports of PPE shortages "fake news." On May 6th, a nurse told reporters gathered in the Oval Office that the availability of PPE was sporadic. Donald Trump said—and this was in the Oval Office—Donald Trump said: "Sporadic for you, but not sporadic for a lot of other people. I've heard we have a tremendous supply in almost all places."

Just last week, Donald Trump said, “My administration currently has zero unfilled requests for equipment, for anything else that they need from the Governors. We are stocked up and ready to go.”

So those are the facts. And the statements that the President has made are just wrong, wrong, wrong.

In the last few days, the Democratic Finance Committee staff has gathered direct accounts from health-care workers around the country about PPE shortages that devastate communities, given the recent spikes we have seen across America.

The committee, for example, heard from nurses in Dallas, TX, where COVID cases are surging, who recently began buying their own surgical masks since the hospital was requiring staff to re-use old ones for days at a time.

The committee heard from an administrator of a 33-bed hospital in rural Alabama, serving a majority black community, who told the committee her hospital is so low on PPE that she keeps an emergency supply stashed in her office for safekeeping.

One Oregon home health-care nurse who did not want to provide their name for fear of retribution from an employer, told the committee they have so few disinfectant wipes that they are cutting them in quarters to last through the week. Imagine that. Cutting disinfectant wipes in quarters so they will last through the week.

Finance Committee Democrats want to make sure these important stories still get heard, so I encourage doctors and nurses and first responders and nursing home staff who are dealing with shortages and defective equipment to submit personal stories for the hearing record at PPEshortages@finance.senate.gov.

If we have learned one thing, it is that getting these stories into public view and in front of Senators can really make a difference. This week, the National Nurses Union released a survey of 21,000 hospital nurses. Eighty-seven percent of the nurses reported having to re-use PPE that is designed for one use.

According to data from the Centers for Disease Control, hundreds of nursing homes did not have PPE in mid-July, and thousands more had less than a week’s supply.

States like Oregon, cities, and health-care providers have been forced to compete against each other and pay a real ransom for equipment on the open market. This has opened the door to junk sold by scam artists and incompetent vendors.

A group of health systems was so concerned about losing access to PPE that it actually bought a minority stake in a big PPE manufacturer just to keep the pipeline open.

So the question becomes—and we have a lot of Senators who represent areas with small hospitals—what about the small hospital and the independent doctor’s office and nursing homes that cannot afford to go out in the open market and buy their own manufacturer?

The Trump administration has touted Jared Kushner’s Project Air Bridge as a PPE game changer, but Project Air Bridge brought in just 4.5 million N95 masks over the course of 3 months this spring.

The Department of Health and Human Services’ estimate—this is the Trump administration—their estimate said that the United

States needed 300 million N95 respirators every month. The fact is, these shortages of PPE have put our doctors and nurses and caregivers in grave danger. An ongoing study by Kaiser Health News and *The Guardian* has identified at least 851 deaths among front-line health-care workers, likely due to COVID-19.

From sea to shining sea, Americans are desperately hoping now that there are going to be safe and successful vaccines on the market in the coming months. They need to be distributed in a fair and methodical and medically sound way.

Unfortunately, the country's experience over the past 5 months, particularly with PPE, raises serious concerns about whether or not Americans can have confidence that the administration will handle things in that fashion.

So there is a lot to talk about today. Before I wrap up, I would ask unanimous consent—I gather, Chairman Roberts, you are going to be running things, so Kansas is out there on both the majority and the minority side. Mr. Chairman, I ask unanimous consent to enter statements on PPE shortages into the record at this point.

[The prepared statement of Senator Wyden appears in the appendix.]

Senator ROBERTS [presiding]. Without objection, it is so ordered.

[The statements appear in the appendix beginning on p. 93.]

Senator WYDEN. And one last thought, Mr. Chairman. I want to also thank Chairman Grassley for adding, at our request, the second hearing on this important topic. We requested it because we felt it was important to hear directly from people who are on the front lines having to face these kinds of difficult choices, and I would just like to close by giving a thanks to Chairman Grassley for agreeing to hold the second hearing on the topic.

Thank you, Mr. Chairman.

Senator ROBERTS. The statement with regard to Senator Grassley is duly noted. It is my privilege now to introduce the witnesses.

First we have Cathy Denning, the senior vice president for Vizient's Sourcing Operations, Analytics, and Center of Excellence. In her role, she provides strategic and operational leadership that guides the philosophy and methodologies for the company's contracting process and related technology, as well as its sourcing, focused research initiatives, and training activities.

We also have Robert Wiehe, senior vice president and the chief supply chain and logistics officer for UC Health. He is responsible for providing both strategic and operational direction for all supply chain and pharmacy operations within the UC Health Enterprise, including the flagship University of Cincinnati Medical Center, Westchester Hospital, and the Daniel Drake Center for Post-Acute Care.

Our next witness is Charles Johnson, who is the president of the International Safety Equipment Association, the trade organization for personal protective equipment and technologies. Mr. Johnson previously served as vice president of policy for the Aluminum Association, acting as their strategic advisor to the industry.

Finally, we have Dr. Ernest Grant, currently serving as president of the American Nurses Association. He has over 30 years of nursing experience and is a recognized burn care and fire safety ex-

pert. Dr. Grant has previously served as the burn outreach coordinator for the North Carolina Jaycee Burn Center at the University of North Carolina hospitals in Chapel Hill.

We will proceed with Cathy. We have two present and two virtual. Cathy, please.

STATEMENT OF CATHY DENNING, R.N., MSN, GROUP SENIOR VICE PRESIDENT, SOURCING OPERATIONS, ANALYTICS, AND CENTER OF EXCELLENCE, VIZIENT, IRVING, TX

Ms. DENNING. Good morning, Senator Roberts, Chairman Grassley, Ranking Member Wyden, and members of the committee. And thank you for holding this critically important hearing and giving me the opportunity to testify today.

My name is Cathy Denning, and I am the group senior vice president of Sourcing Operations at Vizient and a registered nurse. Prior to joining Vizient, I worked as a nurse in both the acute care and home care settings.

Before we start today, I would like to tell you a little bit more about Vizient, the Nation's largest member-driven health-care performance improvement company. Our members include more than half of all the acute care hospitals, including pediatric facilities, community hospitals, and almost all of the Nation's academic medical centers.

Through our group purchasing arm, we help providers by negotiating discounts and other terms resulting in greater value than individual hospitals can typically negotiate on their own. We offer other services which I have outlined in my written testimony.

Today I am focused on the critical issue of the U.S. supply chain during the pandemic, and specifically counterfeit PPE in the gray market that exploits hospitals, patients, and the government with false and often harmful claims of having medical supplies to offer.

When COVID-19 hit, one of our first actions was to set up a war room to field our member providers' requests. We received more than 1,000 inquiries each week, including requested products that members were considering purchasing from nontraditional manufacturers or brokers.

From March 29th through July 13th, we received 1,320 unique member requests for new manufacturers and products. Ultimately, we found that more than 500 of these products failed to meet the applicable FDA or NIOSH standards. And as emergency use authorization changes, so does the complexity of these issues.

This study and validation process was only one piece of our overall pandemic response. And I have included additional examples of our efforts in my written testimony.

Despite our efforts, bad actors still reach out to providers in need, and our members continue to search for the vitally needed safe supplies wherever they can. I will highlight two examples, and there is another in my written testimony.

First, in late March our member Yale New Haven Health learned of possible counterfeit Dasheng KN95 respirators in the market. Combing through their donations, they in fact found that they did have a significant number of these respirators.

They also had placed an order with Dasheng for KN95s, so they immediately canceled those orders. Later, Yale learned that most

of PPE vendors with whom they had been engaging were not actually dealing directly with factories in China, but rather third-party distributors or gray market brokers.

Yale also discovered that many of these vendors had sent in false test results. So that prompted them to send out their masks for their own testing, identifying that only 85-percent efficiency was rated with the mask. And this led Yale to become even more skeptical of these vendors.

Second, one of the large acute-care systems in the Pacific Northwest is still currently sorting out a questionable situation in which they were sent small-sized Halyard N95s from a third-party company. They were in baggies with a seal on them, which was not like they were used to receiving. Halyard usually sends them in a box.

So when they questioned the company about it, they found out that this company said they had a “reallocation process” for those N95 masks. They continued to press. They still have not been able to identify what the issue is. This company is normally a sterilization solutions company, so you can draw your own conclusions from that.

Another burden our members face is the gray marketeers offering products that typically go for 84 cents and trying to sell them to them, like an isolation gown, for \$8.50. And when the same masks that I talked about normally would go for 80 cents, we had offers for as high as \$11 per mask.

There are countless other stories out there like this. But despite the contemptible actions of these bad actors and the overall challenges presented by COVID-19, I would like to end my remarks today with a hopeful outlook to the future.

The health-care supply chain needs three things to be more resilient: enhanced transparency, redundancy, and diversification. We also need to take lessons we learned regarding the strategic national stockpile and do better to ensure that it is truly a resource.

First, we need more transparency into manufacturing locations, raw materials, and storage locations. This information should be made available to the public as well as to the private sector, and not just government entities, so that we can all work towards resilience efforts.

Redundancy of manufacturers is the next step. The best way to achieve availability and cost savings is to encourage competition. The industry needs multiple manufacturers producing the same product so that we do not have one event wipe out the entire supply chain.

Regarding diversification, our supply chain should be global in nature, but we also should strive to significantly increase our domestic footprint across the United States, as well as across the globe.

Finally, I believe the strategic national stockpile does need to be bolstered. The stockpile should have at least 90 days of supply for key items, and the government should continue to engage the private sector to help provide feedback on appropriate quantities and the best storage and management practices. Health-care systems in States need to be able to quickly access these products during a disaster.

With that, thank you again for the opportunity to testify today. I am passionate about these issues and strongly believe that working together, we can all help health-care providers, their patients, and the public get through this crisis.

I would also like to offer my absolutely sincere appreciation for all the front-line health-care workers out there who have given all of themselves tirelessly throughout the pandemic, and I look forward to your questions.

[The prepared statement of Ms. Denning appears in the appendix.]

Senator ROBERTS. Thank you, Cathy.

Our next witness is Robert Wiehe. He is senior vice president, chief supply chain and logistics officer for UC Health. Robert, why don't you now proceed? Robert is also with us virtually.

**STATEMENT OF ROBERT J. WIEHE, SENIOR VICE PRESIDENT
AND CHIEF SUPPLY CHAIN AND LOGISTICS OFFICER, UC
HEALTH, CINCINNATI, OH**

Mr. WIEHE. Thank you, Senator. Chairman Grassley, Ranking Member Wyden, and members of the committee, thank you for the opportunity to speak today about protecting the reliability of the U.S. medical supply chain. As the senior vice president and chief supply chain and logistics officer for UC Health, southwest Ohio's only academic health system, my responsibilities include strategy and oversight of sourcing, acquiring, and distributing all supplies and capital equipment within our health system. Challenges that have emerged from the COVID-19 pandemic are unlike anything we have encountered in our lifetime.

Coronavirus-related disruptions to supply chains, combined with dramatic increases in global demand, are among the many challenges that hospitals and systems are facing in today's environment. While there is substantially more detail in my written testimony, I would like to highlight for you a few challenges and opportunities to be considered by the committee.

As for the challenges, first: hot spots. While southwest Ohio was not an initial hotspot, and that allowed us the benefit of learning from others, it also meant that the region was not prioritized in terms of obtaining limited resources.

As resources were distributed to national hotspot areas, we often needed to engage our elected leaders to intervene on our behalf with Federal leaders and/or manufacturers in order to obtain the items we needed to provide a stable and ongoing COVID-19 response in southwest Ohio.

We view the current medical supply chain for PPE, testing supplies, and machinery as comfortable, not confident. We continue to advocate for a national and State distribution strategy, public and private, that allows resources to be distributed to all geographic regions.

Second: rapid changes in our supply chain strategy. With limited supplies and increased demands, we see how we had to quickly pivot to source PPE from non-standard suppliers. The change was dramatic. It shifted from supplies on automatic replenishment with one vendor to reaching out and making over 500 new sourcing inquiries in a 30- to 45-day period to vendors we had no prior experi-

ence with. This presented the unique challenge of balancing the urgent need for product and the inherent risk in dealing with unknown third parties.

Third: avoiding fraudulent suppliers. Through procuring large items or quantities of PPE in partnership with other regional hospitals, we learned that there were many scams and promises of large quantities of supplies coming in from outside of the United States. These scams involved large sums of money being placed into escrow or cash-in-advance purchases for goods that did not materialize. We saw how quickly it pivoted into a mitigated risk by scrambling multiple smaller orders over various vendors versus trying to rely on a single large purchase to meet our needs.

The majority of the product we successfully sourced came in from China or other Asian Pacific countries. During our vetting process, we found that a significant number of the FDA and third-party testing certificates presented by potential suppliers were not able to be authenticated or verified.

For overseas products during the initial months of the pandemic, we saw several shipments delayed, and our suppliers communicated to us that this was due to supplies being either purchased or seized by the Federal Government. We were not direct recipients of this communication, and we can only attest to what we were told by our suppliers.

Another frequent communication from suppliers was concerning the lack of available capacity with commercial air freight companies instead of limited stockpiles. UC received communication from the ODH in March that the regional and State stockpile was very limited due to expired or destroyed supplies.

In early March, we received our first supplies from our regional stockpile. In late March, we received our first shipment of PPE from the strategic national stockpile.

Lastly: price gouging. I have provided more detail in my written report, but UC Health has experienced increases on price for PPE up to 6 to 10 times the original price.

As for the opportunities, the first is innovation. A great example is the virtual stockpile that was created by the Ohio Hospital Association in partnership with Governor DeWine whereby the hospital industry contributes supplies to a virtual stockpile to ensure that Ohio's economy could open and remain open.

The Ohio Hospital Association coordinates this effort on behalf of their membership. While it is in its infancy, it shows the promise of what true collaboration could look like during any disruption in the medical supply chain. This could expand to a national level and include all parties: government, suppliers, and end users.

Second: greater transparency in the critical supply chains. Reporting of critical raw materials, finished goods, and production capacity for major suppliers would help the Federal Government to better understand critical supply chains and their capacity and ability to react in a crisis.

Third: we favor a more regional approach towards manufacturing of raw materials for critical supplies. Supply chain resiliency must outweigh low cost for critical items. A more regionalized approach to manufacturing would allow for a quicker response when disruptions occur.

Lastly: improved transparency and communication on the national stockpile. Trust is essential for a supply chain to function efficiently. A better understanding at all levels of the supply chain would help to eliminate both fear of the unknown and competition between government and the private sector.

Thank you for the opportunity today to share my insights and experiences. I believe we have already learned many valuable lessons that we can use to improve our health-care supply chain resiliency moving forward.

I am happy to answer any further questions, should you have any. Thank you.

[The prepared statement of Mr. Wiehe appears in the appendix.]

Senator ROBERTS. I thank the witness.

Our next witness is Charles Johnson, president of the International Safety Equipment Association. President Johnson—if I can refer to you in that vein—you are here with us. Thank you so much for being here. Please proceed.

STATEMENT OF CHARLES JOHNSON, PRESIDENT, INTERNATIONAL SAFETY EQUIPMENT ASSOCIATION, ARLINGTON, VA

Mr. JOHNSON. Thank you, Senator Roberts, and thank you, Chairman Grassley, Ranking Member Wyden, and members of the committee, for this opportunity to present the industry's experience during the COVID crisis.

I am the president of ISEA, the International Safety Equipment Association, representing makers and distributors of safety equipment and technologies. For more than 85 years, this industry has stepped forward to aid the United States in the face of emergencies of all types, and certainly for public health emergencies.

When these events occur, ISEA members provide the equipment that protects responders, the medical professionals, and the public. We have battled two major challenges since the onset of the pandemic.

The first is that the safety and effectiveness of the PPE used to combat the COVID-19 pandemic have been compromised, most notably by incredible increases in opportunistic market behavior such as counterfeits, fakes, and fraudulent products.

The second is that the ability of the industry to get the equipment to the people who need it, both in terms of the gross amount of product and the systems which efficiently distribute the products to the end users, has been sorely tested. We have submitted detailed testimony which outlines our experience and our recommendations in these areas. I would like to highlight just a few.

The safety equipment industry is built on a foundation of standardization and trust. Standardized performance is central to the value of the PPE we provide to the wearer. They must understand the parameters of performance for this equipment, and they must trust that it will occur when needed.

Fake, fraudulent, and counterfeit products erode and steal that trust. These illegal products do not just harm the financial interests of our members, they put the end user at risk of injury, sickness, and death. The various efforts to control these activities range from the public sector to the private.

Our own association manages a standardization process which can confirm the legitimacy of products. Those tools and others have been used by various government agencies from CBP to Homeland Security to stop fraudulent and counterfeit products at the U.S. border.

In the U.S. market, the CDC and other agencies have stepped in to surveil the market and to identify fraudulent products. Our own companies have policed the market. 3M Company has taken down 10,000 false and deceptive social media posts, removed 7,000 fraudulent e-commerce offerings, and removed more than 140 deceptive Internet addresses.

Despite these efforts, these practices persist. ISEA supports in general the National Association of Manufacturers anti-counterfeiting efforts, which we have detailed in our comments. It is not just about the products; it is also about the platforms they are sold on.

On the e-commerce front, platforms have been working cooperatively to crack down on illicit products during the pandemic, but that begs the question of why these solutions were ignored for so long. We support legislation requiring that online sellers remove these products and hold the sellers responsible for any injuries arising from their sale.

The second major challenge we have faced is getting the equipment into the hands of those who need it. Our industry has experience with abnormal demand surges, and we are capable of and we have ramped up production. The hard truth is that no planning with existing capacity will address the fact that industries are scaled to meet the regular forecasted demand of their markets, and not to plan for emergencies on this scale.

For these issues, public policy interventions are required, such as the strategic national stockpile. We were an original partner with the Federal Government when the SNS was implemented. Since 2009, we have asked that PPE stocks be properly maintained in the SNS. We support Senator Alexander's Preparing for the Next Pandemic Act, which would provide long-term funding for State and Federal stockpiles, and we recommend that comprehensive, quantitative approaches be included for demand planning.

Some of those approaches could be used now. FEMA needs the authority during a public health emergency to gather data from State and local governments on the supply, use, and demand of PPE.

Regarding the support for domestic PPE production and use, our industry has had a positive experience with the Defense Production Act, used as a tool to help signal demand up the supply chain. Recent results are that funding for both 3M's personal safety division and Honeywell's safety products has more than doubled production of respirators in the U.S.

Broadly, ISEA supports legislation which focuses on direct and sustained support for domestic PPE production. We applaud recent actions to address liability for companies stepping forward to help during a crisis, and we ask that clear reference to gloves and garments be included in the future. And we support tax credits for end users as the American workforce gets back to work, so that they can afford and provide the PPE needed to protect the workforce.

Thank you very much for this opportunity to testify.

[The prepared statement of Mr. Johnson appears in the appendix.]

Senator ROBERTS. Thank you, Mr. Johnson. Thank you for mentioning Senator Alexander's bill. A great number of us, on a bipartisan basis, are supporting that.

Dr. Grant, 30 years of nursing experience. Thank you so much for being here in person. You are next, sir.

STATEMENT OF ERNEST GRANT, Ph.D., R.N., FAAN, PRESIDENT, AMERICAN NURSES ASSOCIATION, SILVER SPRING, MD

Dr. GRANT. Thank you, sir. Good morning. My name is Dr. Ernest Grant. I am president of the American Nurses Association, which represents the interests of the Nation's 4.3 million registered nurses. I would like to thank Senator Grassley, Ranking Member Wyden, and other members of the Finance Committee for this opportunity to be with you here today. I would also like to pay homage to the front-line workers who are still working hard and so diligently.

At the beginning of this crisis, nurses, doctors, and other members of the health-care team recognized that there was a shortage of PPE and began to improvise, using PPE that they made themselves, or using garbage bags for gowns.

Some left the profession due to unsafe working conditions or for protection of their family members or themselves. Some still report suffering emotional, psychological, and mental health stress. Some have also given the ultimate sacrifice. Over 230 registered nurses have died providing care in your communities.

This is unacceptable. Currently, PPE is not being provided in the quantity or quality that is required for nurses to safely provide care for patients. In May, the American Nurses Association conducted a survey, and 45 percent of the respondents stated that their facilities are still experiencing a shortage; 79 percent, or 4 out of 5, of the nurses reported that they are encouraged or required by their employer to re-use single-use PPE, as health-care facilities are stretching their supply of PPE resources. Fifty-nine percent say that re-use of PPE makes them feel unsafe. Nurses should not be exposed to any unnecessary risk in the course of their work. They share human and workers' rights, including the right to be safe at work.

That was 2 months ago. Currently, the ANA is fielding yet another survey, and the preliminary data is showing that nothing has changed. I hear from nurses across the country that the PPE supply continues to be strained.

Colleagues in Oregon report that a large hospital system purchased and reported ample supply of masks. Unfortunately, the hospital switched brands, likely due to supply issues, and the current stock of masks they did receive were all large in size and do not fit or provide adequate protection for most of the staff. Nurses report that the quality of the masks was so poor that the wire that forms around the nose does not fit properly. This causes extreme safety concerns that the facial seal is not tight.

Other concerns that I have heard: nurses being asked to re-use PPE when re-use is not in alignment with manufacturer's guidelines; face masks that fog up, resulting in various incidents; nurses being asked to re-use PPE that has been decontaminated; underserved and rural hospitals being out-bid by larger health systems, as well as both the State and Federal Government, exacerbating their difficulty in obtaining supplies. The list goes on and on.

A major concern from the ANA surveys regards the re-use of decontaminated N95 respirators. There is limited scientific data to determine how many times respirators can be decontaminated without reducing their effectiveness.

As I stated earlier, 59 percent of the nurses say that this makes them feel unsafe. ANA does not support the use of decontaminated masks as a standard practice and urges Congress and the administration to ensure that the country goes back to best practices for infection control as soon as they are able to do so.

Understanding that the PPE crisis is the result of multiple factors such as the shortage of raw material, the global need for equipment, and the growing PPE needs as the country and schools reopen, we believe that more must be done by both the State and Federal Governments to better deploy the protective equipment.

While States certainly have a role in ensuring access to care, more needs to be done to enhance the Federal and the State partnership to ensure transparency and equitable access to safe and quality protective equipment for health-care providers.

Nurses want to, and are willing to work. They just need the protective equipment that will allow them to do their jobs, and do them effectively. To achieve this goal, the ANA recently submitted detailed recommendations to Senator Alexander and the HELP Committee in response to the chairman's white paper.

Our recommendations are outlined in our testimony. I thank you for the opportunity to speak with you, and I look forward to answering any questions that you may have.

[The prepared statement of Dr. Grant appears in the appendix.]

Senator ROBERTS. Thank you, Dr. Grant. You are obviously a champion for the American Nurses Association, and all of the committee thanks you and every nurse in America who has been working overtime with regards to this pandemic and saving lives.

I think I will recognize Senator Wyden at this point for any comments, or any additional questions.

Senator WYDEN. Thank you very much, Mr. Chairman. And, Mr. Chairman, let me begin this way. I believe in the halls of Congress we are always talking about the heroes. And of course we are hearing from health-care heroes, because the extraordinary work they do every day is of such value to America.

But the fact is, we do not send heroes into battle without proper equipment. And yet that is what we have heard from all of these witnesses today. And I know in my home State—and it is just really hard to get your arms around it—we heard from a home health-care worker who says that they are so short of disinfectant wipes that, in Oregon they are having to cut them into quarters in order to actually make it through the week.

So my first question to you, and maybe we will start with you, Dr. Grant, is do you believe that forcing State health departments,

hospital systems, and doctors' offices to compete against each other for medical supplies is a sound national strategy in a global pandemic? Because that is essentially what we are dealing with. The Trump administration has walked away from a strong national leadership role, and so you have these States and hospitals and offices competing against each other.

I would like to have your assessment first, Dr. Grant. Do you think that is a sound national strategy for a global pandemic?

Dr. GRANT. Thank you, Senator Wyden. My answer to that is, no, I do not think that having hospitals, the States, and the Federal Government competing against each other for access to PPE is a sound strategy.

Senator WYDEN. Now the second question I would like to get into is that communities of color have just been hit by the coronavirus like a wrecking ball. And blacks, indigenous, and a whole host of communities where folks have modest resources just really have nowhere to turn.

In my opening statement, I referred to a rural Alabama hospital where PPE is in critically short supply. The CEO there is Loretta Wilson. She runs Hill Hospital in Sumter County, where 70 percent of the population is black and 35 percent of residents live in poverty. There are fewer than 13,000 people living in the county, and 350 have been infected—and 15 have died of the coronavirus.

In my home State of Oregon, the Warm Springs Tribe has a higher rate of coronavirus cases than any other county in Oregon. The situation is compounded by a water crisis, making it harder for members to wash their hands and forcing them to use bottled water. A lot of members of the Finance Committee have constituents in rural communities, and under-served and rural hospitals like Ms. Wilson's are having a very difficult time competing with big buyers seeking out PPE.

I would like to know how this strategy of trying to compete with the big guys seeking out PPE is not just going to compound the racial disparities that we are already seeing? Because those big buyers usually are not anywhere near those communities of color. They are usually out in the affluent white suburbs.

So I would be interested in having our witnesses comment on that, because that is going to be a special focus of the Finance Committee going forward, including in the coronavirus package: the racial disparities that are so profound in American health care. The committee has jurisdiction over health care. You see it in maternal mortality. You see it of course in COVID-19. You see it in out-of-pocket expenses.

But I would like to hear our guests tell us how this is not just going to compound the racial disparity problem, because these big buyers are the ones that are trying to corner the PPE market and are likely to be off in the white affluent suburbs.

Can I have a reaction from our panel on this? Dr. Grant, perhaps you and others could comment on it.

Dr. GRANT. Thank you, Senator Wyden. My initial response to that would be that I would agree with you that the lack of supply directly affects the ability to provide care, and therefore it also makes it more difficult for smaller hospitals such as you described to be able to compete to get the equipment that they need. And as

a result of that, then people who are utilizing that particular hospital for access to health care, obviously they are going to suffer disproportionately because of the fact that they are not getting the quality of care that they should.

So it just starts a snowball effect. But that would be my initial response to you, sir, and I can provide some other information to you after this meeting is over, perhaps, and as we look up some additional data to support that.

Senator WYDEN. I think I am at my time limit, but Chairman Roberts is being gracious. Would any of our other guests like to comment on that—Mr. Wiehe or others?

Mr. WIEHE. Certainly I am happy to comment. I do agree with your comments. UC Health does serve many of the communities that you mentioned. But what we are trying to do, furthermore, is we are reaching out and we are partnering with some of our rural hospitals in the area, trying to help them. They certainly do not have the resources to bring to bear—and you mentioned that—to this crisis. They do not have the sourcing abilities and some of the other things that we can do.

So what we try to do is help them wherever possible to provide supplies, where we are a bit heavy on stock. We are trying to provide them with trusted suppliers that we found through our sourcing activities. But certainly I think your statement is valid.

Senator WYDEN. Thank you. Thank you, Mr. Chairman.

Mr. JOHNSON. ISEA would also comment on the question, if the chair would allow the time?

Senator WYDEN. Yes, I think Chairman Roberts probably will—

Senator ROBERTS. Certainly; certainly. Please proceed.

Senator WYDEN. Thank you.

Mr. JOHNSON. Equipment manufacturers have been very concerned with the design and provision of safety equipment for a diversifying American workforce. And certainly the stresses we have seen on the supply chain during the COVID crisis could have adverse effects on underserved communities.

We do believe that some of the suggestions that have been put forward for better data collection from affected communities of all types across the board can help us alleviate some of these issues going forward.

Senator WYDEN. My time is up, Mr. Chairman. I think that last point by Mr. Johnson is a very good one. The tragedy is, after 150,000 deaths, now we are still talking about trying to collect data. So I thank you for the extra time, Mr. Chairman.

Senator ROBERTS. Senator Wyden, we do not want to leave Cathy Denning out, if she would like to comment.

Senator WYDEN. Oh, yes.

Ms. DENNING. Thank you so much. We serve members from two-bed hospitals all the way up to the largest academic medical centers in the country. And so our efforts have been centered around making sure that, to the greatest degree possible, all sizes of hospital providers were served.

There is just not enough product, as we have talked about. In addition to that, we have realized through COVID-19—we have always recognized that the social indicators of health have been an

issue. But it absolutely has shined a light on the disparity in the people of color area. And so we actually have education sessions that we do for member hospitals around this.

It is absolutely something that we need to address. Thank you. Senator WYDEN. Thank you, Mr. Chairman.

Senator ROBERTS. In making my comments, I would note for the record I remember sometime back when we were considering this kind of a problem, during the Bush administration and at the very last of the Bush administration—this is Bush 2—the President indicated he wanted \$8 billion from the Congress. He made an impassioned plea to start the work to address a possible pandemic.

He said it was not a matter of “if” but “when.” He was pressing on that issue. Unfortunately, the Congress did not respond to his request, although working with the Nunn-Lugar program back in that day on the Emerging Threat Subcommittee of the Senate Armed Services Committee, I was able to go to secret cities in Russia at that particular time—obviously that is not possible today. I will comment on that later.

But my first question is this. As we have heard from the testimony, the increasing demand for personal protective equipment, PPE, caused by the pandemic was unprecedented. And the strategic national stockpile, which I guess the acronym for that is SNS, was not intended to fill the need for every community across the country all at once, even though it was happening in every community all at once.

So I would like to start with a high-level question. Going forward, should we expect and plan for this kind of spike in demand to happen again—I think that is probably obvious—perhaps during the next pandemic? And then how much of that demand should SNS plan to cover? Could stockpiling be too much so as to be counterproductive?

Cathy, why don't you start it off?

Ms. DENNING. Yes, we do believe that the strategic national stockpile needs to be more functional in the future. And so, one of the things that we have recommended is that there be a 90-day supply of critical products—that does not mean all products, which you would typically use in a hospital, but those that certainly you need to get through a pandemic, like personal protective equipment, ventilators, critical drugs that you would need.

In addition to that, we believe that it should be limited to times of disaster and, in those times of disaster, that there is a way for us to get those products quickly to the places most in need.

Senator ROBERTS. I appreciate that. Robert?

Mr. WIEHE. Thank you, Senator. I agree with Cathy's statement. I do believe that the national stockpile needs to be increased. I think 90 days is a good start.

I would also say, I think we need the ability of a complete supply chain from the government. So I think major suppliers, similar to the pharmaceutical industry, should report out capabilities, whether that is capacity, whether that is stock or critical raw materials, so that there is a complete understanding when there are critical shortages even in times of non-pandemic—that the government has a full view of that.

I would also roll that down the supply chain, right? There are possibilities to mandate—potentially to help systems, maybe as part of the CMS mandate—to have a certain amount of stock on hand. I do not think that would be completely onerous on the health system to have that, but I think having this national stockpile spread out from top to bottom in the supply chain would be a logical approach, as we look at this.

Senator ROBERTS. Let's see, we have Charles. Why don't you proceed?

Mr. JOHNSON. Thank you, Senator Roberts.

The obvious answer of course is, yes. And I would go further to say this planning needs to be more comprehensive and systematic. Building on the previous panel of witnesses, this 90-day concept is gray. I would say, "of what?" and "for what?"

So previously we have seen provision of the strategic national stockpile as a sort of one-and-done event. And that has led to expired product in the inventory and other systemic problems.

Going forward, we need a planning process that does a better job of forecasting demand at a much more granular level, that collects information from many more stakeholders, and that addresses those issues with a systemic approach that prices preparedness in to the personal protective equipment industry.

Senator ROBERTS. I appreciate that, Mister—pardon me, President Johnson.

Dr. Grant?

Dr. GRANT. Yes, sir. I would also agree with the other members of the panel. And from our perspective, we support that a report that includes when items are expiring, or when they need to be replaced, should be included in that stockpile so that they are on a rotational basis.

As you remember, some of the reports that have come out earlier when we were accessing the stockpile show that some of the materials had already expired. But as we keep a rotation of supplies going in, we can be assured that supplies are within dates. And as they are approaching their expiration date, then obviously those that still could serve their clinical use can be donated to other health-care facilities or under-served areas, but we want to make sure that the supplies that are in those stockpiles are within their use dates.

Senator ROBERTS. I appreciate that. Dr. Grant—pardon me, I think we have already recognized you. Let me go to the next question really quickly.

Several manufacturers in Kansas—and I am going to include South Dakota here, given that good Senator Thune is present and accounted for—and around the country have altered their manufacturing lines to help produce PPE. And several more wish to do so, I am sure, all around the country.

Mr. Johnson, to what extent does getting more domestic manufacturers to produce PPE solve the supply chain difficulties? What gaps could these companies fill if lines were permanent? And do we see any problems along this line? Please?

Mr. JOHNSON. Thank you, Senator Roberts. ISEA and our members produce in the U.S. We source internationally, some of us, and some of us are international conglomerates.

Our first answer to that question is that increased support for domestic production can be “an” answer to future preparedness, but it is not “the” answer to future preparedness.

Nothing takes the place of proper preparedness planning and provisioning in the future. Now with that said, domestic support and diversification of the supply chain are an obvious plus for the future. And I would once again highlight that a systemic approach to domestic support for the industry will be needed in order to make sure that those producers can stay in business over the long term.

We have seen in previous pandemics that the incredible increase during the emergency leads to huge overhangs of inventory. And those types of strategies that lead to those large overhangs are a perfect way to put that capacity out of business so that it is not available in subsequent emergencies.

Senator ROBERTS. With apologies to Senator Carper, who is anxiously waiting virtually, I want to finish up what I mentioned at the first. Back in the day under Nunn-Lugar, I had the privilege of visiting a secret city in Russia. Those are closed now, of course. But this was a community, or a “center,” if you will, in Obelinsk, where they were—in terms of going in, we were really trying to help those folks keep security and keep these scientists onboard back when the Soviet Union fractured. And there were warehouses full of all sorts of pathogens designed to attack a nation’s food supply.

Now this is an attack, and I guess you could say that, if you really want to stretch this, you could involve China and the United States with this, or the rest of the world. But what worries me is that we had DHS, HHS, and the Department of Agriculture all involved. We had an exercise in that regard, and it was with the livestock community with hoof and mouth disease.

We lost almost every head of cattle in the country. All of our exports stopped. The shelves of our grocery stores were empty. Would any of you like to comment? Obviously we would have a serious problem there, given the fact you would have to use the military. But have you thought about that kind of a circumstance which would be sort of an Armageddon with regards to the situation with a pandemic? And since you answered last, I think I will ask Charles to respond to that.

Mr. JOHNSON. Yes, our industry does contemplate abnormal surge demand in the future and the inventories that are needed to address it.

I would return to the concept that no matter where production is located, it will scale itself to the regular demand of the market that it serves. And so to deal with these issues of large inventory management that is meant to service the surge demand of a large-scale emergency, we have to first have the imagination to contemplate those future emergencies. And then we have to have a rigorous planning program in place that quantifies the needs, and then signals those needs to the manufacturing industry and supports the production of the materials that are needed to respond, or to serve that stockpile. And certainly overshoots are possible and deleterious.

Senator ROBERTS. I appreciate that very much.

Let's see, we have Senator Carper. Senator, I apologize for going over time.

Senator CARPER. That is quite all right. You are a chairman. You can go as long as you want.

To our witnesses, especially the ones from the Queen City of Cincinnati, we welcome you. I am an Ohio State boy, and I am just glad to have a Buckeye in the house. Thank you all for joining us from around the—

Senator ROBERTS. Tom, let me interrupt you. We need to get sound up, if we can, on behalf of Senator Carper.

Tom, can you speak up a little bit?

Senator CARPER. Yes, I can. I want to start by—for my sound check, I want to quote Einstein. Einstein used to say that the definition of insanity is to do the same thing over and over again and expect a different—what?—result. Einstein also said, "In adversity lies opportunity."

We are facing one heck of a lot of adversity here, but there is also some opportunity as well. And I want us to focus a little bit on that opportunity.

Now was that—in terms of my sound, was that any better, Mr. Chairman?

Senator ROBERTS. I'm sorry, Senator, not at least as far as I am concerned. We are having some problems.

[Pause.]

Senator CARPER. I am going to try—I have a Lavalier mic on. I am just using that. Is that any better?

Senator ROBERTS. Senator, pardon me. I asked them to turn the sound up, so now we have an echo. But at any rate, what is your specific question? If you want additional time, you can have it, or if you want to reserve your time, you can have it.

Senator CARPER. I want to make sure you can hear me. Can you hear me?

Senator ROBERTS. Yes. Yes, we are in good shape right now.

Senator CARPER. Thanks so much.

Senator ROBERTS. Thank you.

Senator CARPER. This Lavalier mic has helped. I was quoting Einstein for part of my sound check, and a couple of Einstein quotes: the definition of insanity is to do the same thing over and over again and expect different results. The other Einstein quote: in adversity lies opportunity.

Given all the adversity we have, there has to be some opportunity as well. And one of the great things about this panel is, you can help us to identify some of that opportunity.

We continue to hear from the administration about how good the response has been to the coronavirus pandemic, yet the U.S. continues to be the country with less than 5 percent of the world's population and over 25 percent of the deaths around the world. And since March, my colleagues and I have been calling on our President to invoke something called the Defense Production Act to expedite production of much-needed medical supplies. And almost 5 months later, the country is still faced with PPE shortages, and you have shared responses about results today. And we certainly see that in Delaware as well. But we thank you for joining us, and

I want to thank our chair and ranking member for bringing us together.

Sometimes when we have a panel like this with really smart people and a big problem to solve, I will ask, where do you agree? For each of you, give me one example where you agree. You heard one another's testimony, things we ought to do more of, less of. Where do you find there is a consensus in maybe one area, Ms. Denning, that you would really especially recommend we take action on, really follow up on? Ms. Denning?

[Pause.]

Dr. GRANT. If I may be at liberty to answer the question first, I believe that more transparency in reporting is needed to help fix the supply strain that is going on. You know, obviously the reduction of competition between the State and Federal Governments, which is also causing problems with health-care facilities having to bid against larger entities. That is obviously driving up the cost of the mask, and sometimes driving it out to where they are not able to make those purchases.

So I would think that more transparency and being able to work together so that everyone can get a piece of that.

Senator CARPER. Thank you, Dr. Grant. I think that—Cathy Denning, you are next—I think that was like maybe the first point that you made. Is that correct?

Ms. DENNING. That is correct. We believe that not just transparency for certain agencies, but for everybody really around where the product is manufactured, where those raw materials come from, how you get it through the supply chain. And really, we ask suppliers to provide us with the time that it leaves the manufacturer to the dock of that hospital. We have had a very hard time getting that information.

I think the other things that I would add—transparency is one part of resilience. But also we need a global supply chain that is redundant, with an increased domestic footprint.

We do not believe that even if we wanted to, tomorrow we could add all of our manufacturing back onshore, but we do believe that there is an opportunity to significantly increase that. Vizient actually has gone at risk with several domestic manufacturers guaranteeing the purchase of their product if they would bring up lines in North America.

We can do more of that. It certainly is a gap filler, but we have made long-term commitments to those companies, and I think that is something, echoing Dr. Grant, that we would need to make sure of, that there is an opportunity for hospitals to continue to buy products as we are—

Senator CARPER. I am going to ask you to hold it right there, please. We need to have time for these other folks. They will not be very happy. They will go home sad.

Robert Wiehe from—where are you from? Where are you today, Mr. Wiehe?

Mr. WIEHE. I am in Cincinnati, OH, Senator.

Senator CARPER. Okay, good; a buckeye.

Mr. WIEHE. Thank you for your thought for the Queen City.

Senator CARPER. You bet. You bet.

Mr. WIEHE. I think my response would be very similar. Thank you.

Senator CARPER. All right. We are hearing greater transparency. We are hearing redundancy from two of our witnesses. Would you agree with that?

Mr. WIEHE. I agree completely. I think, as was stated previously, there is no wrong answer here, right? I think transparency is critical. And that transparency is not just from the supplier base, but from the demand side as well.

We need to be consistent in what we are telling folks is needed.

Senator CARPER. Charles Johnson?

Mr. JOHNSON. I would echo that last thought. I think that we are all in violent agreement on this transparency and data issue. I think that we all—

Senator CARPER. I love that term, “violent agreement.” That is wonderful.

Mr. JOHNSON. We see it all from different facets of the same issue. From the manufacturing side, what we have really learned through the COVID crisis is that we need a lot more transparency about the demand signals coming from users. Because without that, industry is flying blind, and distributors are flying blind.

And so from our point of view, that transparency applies to communication up the supply chain from the users, from the States, and from the various actors that are at the other end of the supply chain.

Senator CARPER. All right. I would ask one more question, if I could. I think I have some time.

Coordination of the Federal Government—this would be for you, Mr. Johnson. My staff and I have spent a fair amount of time—and I am sure other staffs and the members have too—since this pandemic began, working with the FDA, working with CBP, and even the State Department, to try to retrieve shipments of medical supplies and test kits that have been blocked by Federal Government officials.

During any global pandemic, we ought to expect new technologies and supply chain backlogs that challenge our regulatory systems and overload our border checkpoints.

Having said that, I know we can do better. In your view, what sort of coordination is needed to ensure that delays are minimized, appropriate treatments and tests are approved, and regulations are clearly communicated for those attempting to provide our front-line workers with needed supplies?

Mr. Johnson?

Mr. JOHNSON. That is a great question, and thank you for asking the question, Senator.

The ISEA and our members have had a long and productive partnership with various Federal agencies that manage the certification of, the approval of, and the regulation of safety equipment.

Greater coordination between those agencies during the COVID crisis could help other entities that are policing the U.S. border—or are surveilling the U.S. market—to carry out those activities. We have seen unintended consequences during the COVID outbreak.

We have seen shipments of legitimate product held at the U.S. border. In some cases, this was because they were erroneously thought to be classified as medical products by the FDA and thus would need FDA approval for movement across the border, when that was not in fact the case.

ISEA has been able to help in those situations, but clearly the fact that it occurred to begin with points to the fact that we need better communication about the legitimacy of safety equipment products and the proper processes for policing those issues when they do occur.

Senator CARPER. Mr. Johnson, I am going to ask you to wrap it up right there. My time has expired.

Mr. Chairman, thanks so much for your generosity with the time. My thanks to the witnesses. Great to see you all. Hope to be able to thank you in person for the great work you are doing around the country. God bless.

Senator ROBERTS. Thank you, Senator. And we are going now to Senator Cassidy, who is going to assume the role of acting chairman. Senator Cassidy, as I understand it, will be with us virtually. Senator Cassidy?

Senator CASSIDY [presiding]. Senator Roberts, thank you. And now it is Senator Cardin's turn to ask the questions.

Senator CARDIN. Thank you very much, Mr. Chairman. And let me thank all of our witnesses. This is a very, very important issue, for us to get the supply chain right.

I am just going to start off by giving one example from one of our hospital groups in Maryland, and they gave me their dollar numbers in regards to what is happening with PPE.

Face masks have gone up 20 times. Face shields have gone up 5 times. Respirators have gone up 10 times in cost. Isolation gowns, 10 times in cost. And gloves, 4 times in cost.

So where their 2019 total expenses for PPE were about \$800,000, so far, in the first 5 months, their costs are \$11 million. Now part of that is volume, and part of that is the extraordinary increase in costs because of the inadequacy of the supply chain.

I want to concentrate on an issue that some of you have already touched upon. Senator Wyden brought this up. And that is, the disparate impact it has on minority communities and under-served communities.

Senator Menendez and I have introduced legislation to deal with the COVID response to minority communities, recognizing that they have suffered more on a population basis from COVID-19, but also the distribution of PPE and many other issues, the testing supplies—all that has put these communities at greater risk.

You all have acknowledged that, but you have not given us a plan to try to counter that, other than the general issues of dealing with the supply chain, which I strongly support. But I can tell you that if we just deal with the supply chain, we will not be dealing with the unique problems we have in under-served communities. They still will not get the same quality and quantity of PPE, and they certainly will not get the same access to testing and health care.

So can you give me some concrete suggestions on how we should target our response to deal with the under-served communities and the minority communities?

I think I will start first with Dr. Grant, if I might. If you could help me on this, I would appreciate it, because we are looking for specific ways we can target the help to those communities that have suffered the most.

Dr. GRANT. Thank you, Senator. I would be happy to give you some suggestions that we feel would be most helpful.

The first is, obviously there needs to be a stronger investment within the public health sector. I believe that public health funding has been cut dramatically since, probably about 2008. So an investment in that would allow for more nurses to be in the community to promote the help in health care that is needed.

Obviously investing more in testing, and test follow-up, or contact tracing follow-up is extremely important as well. And again, having enough funding for nurses to be able to do that.

And I think the third thing would be—I cannot emphasize enough—for nurses to be at the table when these decisions are being made. When you have local committees, or even at the State level, as they are identifying these communities of high risk, the nurses know the communities very well and can identify either potential hot spots or how to access those communities. So it is extremely important, I believe, that we take those two things into consideration as we are looking at ways to invest in the disparate communities.

Senator CARDIN. That is very helpful. Let me just point out another serious challenge we have. We find that minorities have much higher representation in industries in which they have essential workers who have worked—we had significant problems in some of those plants in Maryland. And we found that those employers either were not in the position, or did not pay attention to having adequate protective equipment for those workers.

So let me just drill down as to what role the Federal Government has, either in requiring or help with financing to make sure that those vulnerable workers have the protective equipment they need.

We know we have the health-care workers, and they are not receiving the adequate supplies. We know we have the nursing homes, included under the health-care workers, that have been made vulnerable. But we also have businesses that have been there providing essential employment, but they have not had the ready supply of quality equipment for their workers.

And is there a role for the Federal Government to play, either in regulation or in financing, or both, in order to provide better protection for these essential workers who may not quite have the same voice for protection as other workers have?

Dr. GRANT. I would agree with you, Senator, that there is a role, such as perhaps congressional oversight, as well as adequate funding to ensure that relevant agencies are able to stay focused and follow through at the local level to ensure that the services that need to be offered at the local or regional level are done to the fullest of their capacities. So yes, I would wholeheartedly agree with your comments, sir.

Senator CARDIN. Thank you. And let me again thank all the witnesses. And, Mr. Chairman, I will yield back my time. Thank you.

Senator CASSIDY. I have to be here, so I am going to allow my colleagues to go before me. So, Senator Brown, I will call upon you now.

Senator BROWN. Thank you, Mr. Chairman, and thanks for—

Senator CASSIDY. Excuse me, Senator Brown. Can we reset the clock, please? There you go. Okay, Senator Brown; I am sorry. Go ahead.

Senator BROWN. Thank you. And thanks for your generosity, Mr. Chairman.

Mr. Wiehe, thank you for the work you do in Cincinnati. We know the failures, and I hear far too many times people—whether they are working in hospitals or working in grocery stores, whether they are bus drivers or custodians or security workers or food preparers—simply have not gotten the masks and the other kinds of protective equipment they need due to a failure of the President when, back in March, we asked the President to begin to use the Defense Production Act and to scale up both testing and things like producing cotton swabs and protective equipment. And the fact that we are still struggling as this outbreak continues speaks to that.

I wanted to ask you, Mr. Wiehe, as the Federal Government works to strengthen the strategic national stockpile or domestic supply chain, what should we prioritize?

Mr. WIEHE. Thank you, Senator Brown. Again, I am going to sound a bit redundant with my response. I think transparency and communication have got to be strengthened. And I am going to elaborate on that a bit more than I have.

While we have received some goods from the strategic national stockpile, they have been sporadic; they have been unannounced. For a supply chain leader, when you are not able to plan because you do not know what is coming, you have to assume it is not coming, right? So it leads to us procuring all of our needs versus maybe relying on something else.

I think that leads to competition. So I think the transparency and good communication about the strategic national stockpile has to be improved. We have to understand it a little bit better. We have to understand what is forthcoming, or how we can rely upon it. I do think, as we have talked about earlier, that resiliency in bringing some or all of the production regionally into North America, or into the United States, is critical because that allows a supply chain a much faster response time when there is a period of demand that we have not seen in the past.

I think, lastly, just having the right quantities in the stockpile, having goods that are not expired—and again, so that we are not competing with the government and the private sector for those same goods when a pandemic or another crisis hits. That is crucial.

Senator BROWN. Thank you, Mr. Wiehe. Thank you for that. I introduced yesterday the Protecting American Heroes Act, which would increase U.S. production of PPE and other critical items in the strategic national stockpile. And the legislation would strengthen the supply chain resiliency and make sure we are better pre-

pared for a pandemic. So I look forward to working with you, and UC, and others. So thank you for that.

Dr. Grant, in testimony you submitted to the House Energy and Commerce Committee hearing earlier this year on health-care inequality, you urged Congress to identify and address racial disparities in its Federal response to COVID-19. Thanks for your dedication to addressing that.

How does Congress ensure future policy decisions—from those specific to COVID-19 to those designed to eliminate racial disparities—how do we ensure those decisions are informed by diverse scholars and experts, including our Nation’s nurses?

Dr. Grant?

Dr. GRANT. Thank you for that question, Senator.

I would say that one of the best ways that Congress can ensure that is, obviously, funding that would ensure that health disparities are addressed and become a top priority and not just a sub-tier priority. But particularly illnesses that affect minority communities, and the disparate communities, that those issues are addressed, and that we see a change in the focus of health care—mainly, a focus towards prevention and education in those particular areas so that better health and better care can be provided for everyone.

Senator BROWN. Thank you, Dr. Grant.

In closing, Senator Cassidy, I would like to briefly comment on something the President said in a news conference yesterday afternoon.

He said, and I quote, “We’ve replenished the long-neglected national stockpile. In January, the stockpile had 17,000,095 masks. Today the stockpile has over 50 million masks. We will be doubling that in a very short period of time. And then doubling that number again,” is the President’s quote.

If that is true, the question is—to no one in particular—but the question is, why on earth are we still forcing our nurses to use poor quality PPE or to re-use their equipment? I mean, it again sends the message to workers in this country that we may call them essential but they really seem expendable. And Congress needs to do something about that.

Thank you, Mr. Chairman. Thank you, Mr. Wiehe and Dr. Grant.

Senator CASSIDY. Thank you, Senator Brown. The time has expired. Senator Brown, did you want an answer to that, or can we go to Senator Cortez Masto?

Senator BROWN. No, I was really just putting the question out there of, what are we doing? So thank you, Mr. Chairman.

Senator CASSIDY. Okay, your time has expired. Thank you, sir. Senator Cortez Masto?

Senator CORTEZ MASTO. Thank you, Mr. Chairman.

Thank you all for participating today. I can tell you, the conversation we are having today is the same conversation we are having in the States. And I think every State and every local government, everybody is competing with one another—

Senator CASSIDY. Excuse me, Senator Cortez Masto. Can somebody start the clock, please? Got it. Okay, I am sorry.

Senator CORTEZ MASTO. You bet. Thank you.

So I am a firm believer that we should have fully invoked the Defense Production Act, and that would have addressed all of the concerns we are hearing about right now. So I appreciate the conversations we are having.

And let me just say for the record as well, in the State of Nevada, what you are talking about with the lack of communication from Federal agencies, we are seeing it. We had to compete to get PPE in the private sector, which was held up at the border.

And then we, thank goodness, had a good working relationship with our FEMA regional director who helped us move it from the border to get it to Nevada. I mean, everything that you are all saying is absolutely happening in all of our communities. I cannot thank you enough for using your voices to really stress this, and why we need to fully invoke the Defense Production Act, and why we need one single command and control over all of the supply chain, from the PPE to the tests to everything else.

We as a country have done it in the past, and that is why we should be doing it now. So my question to all of you on the panel is, is it too late? Is it too late for us to fully invoke the Defense Production Act and address all of the concerns that we are hearing now?

Let me just open it up. Let me start with Ms. Denning.

Ms. DENNING. Thank you, Senator. What I would say is, I am not familiar with all of the nuances of the Defense Production Act, but any time that we can increase production and make available products that are critically needed by the front-line health-care workers, and the public in general, I would support that.

I will give you a statistic. I heard you talk about the N95s. Here at Vizient, we have been tracking what the use is of N95 masks. So to give you an example, normally our hospitals, which represent 50 percent of those acute-care centers in the country, would need 50 million N95 masks in a year.

Most recently, our count for this year alone is up to half a billion—so, 500 million masks. So when you think about how staggering that is, that need of the hospital, anything we can do to meet that need in any way, I would support.

Senator CORTEZ MASTO. Thank you. Let me go to the rest. Mr. Johnson?

Mr. JOHNSON. Yes, thank you for that.

I want to stress that our members and our Association have been active and positive participants in the DPA process that has been in use, and we stand ready to partner with the Federal Government if it is invoked further in the future.

And we can say unequivocally that it has helped. And there is new capacity that is coming online through the use of the DPA. We would also say, as an industry, that the DPA is not magic. It cannot stretch back into the past and make production lines appear out of thin air.

And so I would say that, given what it can do and is doing, and if there are future solutions that are proposed for the use of the DPA, we would absolutely want to partner there. But command and control for capacity that does not exist is not a solution.

So again, we are positive and active participants in this process. We want to partner more in the future, and we absolutely will. But

we want to stress that it cannot make production appear out of thin air.

Senator CORTEZ MASTO. Right. And that is the problem, right? I mean, that is what we knew going into this from the very beginning. It was about production. Yes, command and control is important, but it starts with that production and that capacity, and controlling it.

I mean, again, we have done it before as a country. We did it with the Jeep, right? And so what we know is, it is doable, and that is the whole reason we have this act. But let me move on here, because I only have so much time.

And let me ask, Dr. Grant, I think we all are so deeply concerned about the impact that this pandemic is placing on our health-care workers, our nurses, everybody on the front lines who are the true heroes.

But let us talk a little bit about the psychological toll on nurses who are caring for patients through the pandemic. What can we do to address the mental health needs of nurses and other health providers that we should be aware of? And what more can we do? Because we know that, besides being on those front lines, they are also dealing with emotional issues when it comes to individuals who are positive for COVID-19.

Dr. GRANT. Thank you, Senator. I would like to emphasize the need for more spending on mental health services for front-line workers. This pandemic, as you have stated, has placed a tremendous strain on providers, including the registered nurses who provide the individual care.

Our foundation has actually recently just completed a survey, and over 75 percent of the people who responded to that survey are showing high stress, post-traumatic stress: not being able to sleep, not being able to eat, or sleeping too long, short tempers, et cetera.

And what this does is, it leads into the fact that when they do go to work, they are not able to work as effectively as they can as a result of this. So definitely more funding is warranted to address the mental health needs of the people who are on the front line.

The downside to that, unfortunately, may be that more people may choose to leave the profession, and Lord knows we need all the nurses that we have at this particular point in time. So I am extremely concerned about the mental health needs of our front-line providers.

Senator CORTEZ MASTO. Thank you. I know my time is up. Thank you so much.

Senator CASSIDY. Thank you. Senator Casey?

[Pause.]

Senator CASSIDY. Senator Casey, you are muted.

Senator CASEY. Oh. Okay now?

Senator CASSIDY. You've got it.

Senator CASEY. Thank you, Mr. Chairman. I want to thank the witnesses for their testimony and their ongoing work on this issue. And we can recite chapter and verse about the failures of the last several months, and they are many on PPE.

But we also have to acknowledge that we have not had the manufacturing capacity in place to meet the demand. So we hear from, as every Senator does, hospitals and nursing homes and all kinds

of settings. And frankly, we need a whole new industrial policy when it comes to PPE. We have to stop thinking about this in terms of months or years. We need to be building up for decades of PPE.

That is my view of it. But we are hearing a lot about strengthening the supply chain. We are hearing about stopping counterfeit products, both of which are critical debates to have. But we are also hearing a little bit, and frankly not enough, about investing in the next generation of PPE.

So I am going to start with Mr. Johnson. We have been considering today the challenges with supply and quality control as it relates to PPE, and the critical role it plays. But I want to ask you a question about innovation.

What is the status of PPE innovation right now? If you could, kind of outline that for us.

Mr. JOHNSON. That is a wonderful question, and thank you for that. The PPE industry is always innovating. And even during the COVID crisis, new solutions and alternatives have been brought to market. And solutions that were used in other sectors have been redirected into the COVID crisis response.

And so that innovation is always occurring. And I would say, proudly, that ISEA members, and U.S.-based personal protective equipment manufacturers, are world leaders in innovation in this space. And that is the strength of the U.S. PPE industry.

So we are already making those investments, and we are already looking forward into what the next generation of PPE may look like. We are also working especially for respirators, which have been so much in discussion during this pandemic. We are working closely with the regulatory bodies that also carry out research in that area. And we fully support funding for those agencies. And I am speaking specifically for the National Institute for Occupational Safety and Health, and NPPTL, where respirator certification and research takes place.

Senator CASEY. Mr. Johnson, what, if any—and I hope the answer is there are not—but what, if any, barriers exist to PPE innovation?

Mr. JOHNSON. That is also a great question. Barriers do exist. The certification process for respirators is a process that we have worked closely with the Federal Government on in the past. It is a process that has in the past suffered from long lead times.

I would note that proper funding for the agencies that carry out that work, so that they can carry out their mission, so that new and innovative products can be brought to market faster, would be a great intervention to help innovation in this space.

Senator CASEY. Thanks very much. I want to move in the remaining time I have to Dr. Grant.

We know from some of the background materials you have provided that health-care workers are concerned about both quality and durability of some foreign-made equipment. We have also been hearing from front-line workers that, as they wear the PPE over many hours or days, their masks become uncomfortable and cause long-lasting skin irritations.

What have you heard from nurses about improving the design of PPE for health-care workers?

Dr. GRANT. Thank you, Senator. We have had a couple of comments from nurses, you know, asking for ways to try to be in on such a design change, if you will. Obviously, wearing a mask for up to 12 to 16 hours a day, you are correct in that it does leave an imprint in the face. It also causes hypersensitivity reaction to the skin.

And again, you are looking at masks that are just designed to be used once and thrown away. So the fact that we are re-using them and, depending on what they may be decontaminated with, as well as what may be remaining in the material, could be causing that irritation.

So we would welcome the opportunity to get with the manufacturers and see if there is something that we could do that would help to minimize such reactions from occurring.

Senator CASEY. Thank you, Doctor. Thank you, Mr. Chairman.

Senator CASSIDY. Senator Whitehouse?

Senator WHITEHOUSE. Thank you, Chairman Cassidy, and thank you to the witnesses who are here.

We had some pretty compelling testimony yesterday about the state of the PPE market. It was described as being rife with counterfeiting, with crime, with price gouging. Several investigative efforts have been stood up to try to deal with the criminal activity that runs throughout this market.

And I wanted to ask the witnesses—so I will start with Dr. Grant, if I may—for their view of what this PPE marketplace looks like. And I will say, by way of introduction, that from Rhode Island, which has actually handled the COVID crisis better than most States, we are seeing descriptions of this marketplace that are chilling.

People refer to it as “the dark side,” as “dog-eat-dog,” as “Lord of the Flies competition.” And if you would take a second and think about it, if the market is that toxic, it does not just affect the demand side—the hospitals that are thrown into this mess trying to fend for themselves and find their own equipment—it also affects the supply side. We have a powerful textile industry in Rhode Island. They are trying to find their way in. But it is very hard to not know whether you are qualified, to not know what the standards are, to not be able to get in touch with somebody who can assure you that your product will sell, to not know that there will be a market for it.

My thesis here, from what I have been seeing in Rhode Island, is that when a market goes toxic—and my belief is that this one has gone toxic—it not only discourages the demand side of the market, it discourages the supply side of the market.

All of this could have been resolved by a more potent, forceful, and sensible executive branch response, but let us not get into that. Let us just focus on—to your people, what does this market look like? And does this “dark side,” “dog-eat-dog,” “Lord of the Flies” terminology pertain from your perspective?

Dr. GRANT. Thank you for the question, Senator. From the perspective of the nurses and other front-line workers, this creates a lot of concern because, obviously if you are getting equipment that is not in good quality, that does not fit very well, then of course you are concerned about the possibility that while you are actively

taking care of someone who has a known case of COVID-19, what is the potential if there is a break in that seal, if you will, that now you are at increased risk for that?

Obviously, as there is also more of increased demand or more people getting in on the black market, then that means that perhaps less quality equipment is getting there. I also have been told from staff that a public affairs firm is working to try to get PPE into the giant box store corporations, and that is causing a great deal of concern, because I am worried about the fact that now large box chains will be able to outbid hospital systems and take more masks away from them or continue to drive the price up.

So your comments are very well-founded, sir, and it does cause an extreme concern for me and for those who are on the front line that not having, not only quality but quantities of PPE that they need to do their job and do it effectively, is going to create more psychological impact. And as I stated earlier, the possibility is that some nurses may choose to leave the profession, which is of grave concern to me.

Senator WHITEHOUSE. Mr. Chairman, if I could, I would like to ask the remaining witnesses to take this as a question for the record and offer a written response, if they would care to, because my time is running out. But I would point out, in my last 40 seconds, that in Rhode Island—again, less hard hit than many places; more successful in dealing with it than many places—we had PPE trucks from FEMA show up empty.

We had deliveries to our providers of counterfeit and defective goods. We had people who had to offer payment for products in order to get in line, and the products never showed up. The thing was a scam. And then they have had to fight to get their payments back.

The market, I believe, is toxic. And it is toxic because of an absence of Federal leadership to oversee a legitimate market with proper supply and demand.

And with that, I will leave it to the witnesses to provide the written responses, and I thank the chairman.

[The responses appear in the appendix.]

Senator CASSIDY. Thank you very much, Senator Whitehouse.

Senator HASSAN?

Senator HASSAN. Well, thank you very much, Chairman Cassidy, and to the ranking member, and to all of the witnesses. Thank you for participating today.

The challenges we have heard about from our witnesses today clearly convey the shortcomings of our current supply chain. And I will add to what my colleagues have already said. It reinforces the need for this administration to take strong action to support the acquisition and distribution of medical supplies, including personal protective equipment.

At any point over the past 5 months, this administration could have invoked the Defense Production Act. And I will continue to call on them to take that step, which would provide support to health-care workers, hospitals, and suppliers and would address many of the issues that we are hearing about today.

And I also just want to add that, while we are focused on the health-care sector today, I spent time this week talking with my

education leaders in New Hampshire, and they are going to need PPE if we are in fact reopening our schools for physical attendance this year.

And that again adds a whole other source of demand in an already highly stressed system. So my first question is to Ms. Denning.

Given the increase in demand for personal protective equipment and the challenges facing our supply chain, group purchasing organizations have had to adjust their allocations to health-care facilities, which means their customers are almost universally receiving less than what they order. How are you prioritizing these allocations to ensure that PPE and other essential supplies are getting to facilities that are experiencing shortages or are in the midst of a COVID-19 surge in their community?

Ms. DENNING. Thank you, Senator Hassan. We do not actually set allocations; the manufacturers and the distributors work together to do that. What we identified is that, regardless of historical usage—so your allocation is based on your 3 prior months of usage—there just is not enough allocation to a particular health-care facility to meet the demand.

So when we find that a member—we call them members—a member provider is short on product, they will reach out to us. We work with the suppliers and those distributors to identify product that is potentially available and help get that to them in the most efficient and effective and quickest manner.

Just this week, we had a large hospital system down in southern Florida that had 3 days' worth of exam gloves left, and so we worked with a new supplier that we had done a contract with to get them supply. I will tell you, there just is not enough supply right now.

Senator HASSAN. But let me ask you, then—this is a follow-up. I am sure it is incredibly difficult to balance all of this as a purchaser, but is the Federal Government helping you identify and prioritize facilities that are facing the most urgent need for supplies? And how has uncertainty impacted your acquisition costs?

Ms. DENNING. Yes. The Federal Government has not stepped in to help us, but they have stepped in to help different hospitals. We have heard about FEMA helping them. We have worked with FDA and Customs and Border Patrol, OSHA, in order to ensure that information was available and if we had products that were not getting across the border.

It has impacted us from a cost perspective. I will echo what everybody has said. The underbelly of the supply area has come out through this. And so we see people trying to profiteer. Vizient, though, does not do contracts with those gray market suppliers.

We work with bona fide, known suppliers and attempt to find a middle ground to make sure that we continue to have supply for the increasing and ongoing demand at a fair price for everybody, given the current market.

Senator HASSAN. Understood. And has that lack of centralized Federal planning to sourcing and allocating personal protective equipment impacted your ability to source products from your traditional suppliers or identify new suppliers of safe products?

And just quickly, please, because I need to move on to one other question.

Ms. DENNING. Yes. I think we could have done better there.

Senator HASSAN. Dr. Grant, I just wanted to add my thanks to you and the nurses all across the country who are putting their own health on the line in order to respond on the front lines to the COVID-19 pandemic. We are very, very grateful for the work you are doing.

We have certainly been hearing from health-care workers about how this virus will impact their own health and that of their families, and how these challenges have been more difficult in an environment where access to PPE has become less certain.

We know that there is enormous stress and strain and mental health challenges as a result on the front-line nursing workforce, but could you address, sir, just how the uncertainty about how much personal protective equipment, what kind and quality of personal protective equipment you are getting, and the need to re-use it when it is not traditional practice to re-use it has affected the mental health and the trauma that your members are experiencing?

Dr. GRANT. Thank you, Senator. As I pointed out in my opening statement, about 59 percent of nurses who responded to a survey that we did stated that their use, or re-use, of a mask that has been sterilized makes them feel unsafe.

When they are feeling unsafe, then that is in the back of their mind, which also may interfere with their ability to perform their job effectively. There is always that potential question of, is this the time that perhaps I may catch the virus, as opposed to knowing that I am using a brand-new mask to reduce that chance?

So it is very, very stressful for them. And this is why we are advocating that we increase the supply chain so that nurses are able to get a new mask every time that they can, as opposed to sometimes being forced to keep the same mask for up to 10 days to 2 weeks. It is just really unconscionable that it is being asked of a health-care provider to do that.

We do not send firefighters into fight a fire without the proper gear. The same thing with nurses: they want to be able to do their job. They just need the proper equipment to be able to do that.

Senator HASSAN. Thank you. And thank you, Mr. Chairman; I went over. I appreciate it.

Senator CASSIDY. Senator Portman?

Senator PORTMAN. Thank you, Mr. Chairman.

First of all, Rob Wiehe, thank you for coming to testify. It has been great working with you and Dr. Lofgren and other folks at the University of Cincinnati over the past few months to address this unprecedented pandemic.

And I was pleased that we were able to get the great testing equipment, way back in March. You all contacted me and said that you had ordered a test, and that you were told by the folks, at Roche in this case, that they had to take the test somewhere else at a time when we were desperately needing it in the southwest Ohio region.

So I am glad we were able to get that test by getting HHS involved. And I am glad we have great testing in Ohio. We have now

gone from about 8,000 tests a day to about 22,000 tests a day. I think that was the average the last week, in the space of about 6 weeks, and that was needed.

The problem is, the people are not getting the results quickly enough. And I want to talk to you about that. That is certainly the information I have. Some of it is anecdotal, I will acknowledge, but it is basically people who say, "Look, I can now get a test. I went to the pop-up testing center." I am glad we have those now, and we have used some Federal money for that, some of the money that came out of the CARES Act, but we have to know the results more quickly than 6 to 8 days in order for it to be effective.

Someone told me about their kid who had to take a test in order to go back to a sports team, but the results came so late that they had to be re-tested again. And I do not get that. I mean, we are finally getting the testing up to where we all want it in our States. I would still like to see even more testing, because I think that is essential to getting us back to work safely, and back to school, and back to using health-care facilities, and in general leading a more normal life. But I think that not having the ability to get the results quickly enough really undermines those efforts.

And again, in some cases people have had to test and re-test, including some of the companies that have asked for testing, and I am just talking about the diagnostic test here. I am not even talking about the immunity test, which has other issues we can talk about in terms of its accuracy.

But one, Rob, if you could just tell me, do you agree with the information that I am getting with regard to the timing on tests, how quickly people get results of their tests? Is that accurate, from your experience and the data that you have?

And then second, if I am right, I want to then dig a little deeper into why. It is the re-agents; it is having the technical expertise, having the technicians available. It is just the machines like the one you have being overwhelmed with the number of tests, I am told.

But I want to get your perspective on both of those things. So, Rob, could you give us a little help there?

Mr. WIEHE. Yes. First of all, I would like to say "thank you" again, Senator Portman, for helping us with the Roche diagnostic equipment. It was much-needed in the region here.

So I do agree, there is a lot of variability with the timing of getting test results. And what we are seeing—we have the Roche machine, as well as some other machines, in house. We are on allocation on most of our testing supplies. And it presents some difficulties with planning for our lab.

The Roche machine, for example—we have folks on all three shifts who can run that. It is, as I understand it, a little easier machine to run than some of our other equipment. But if we do not know that we can get supplies on that piece of equipment regularly, planning for that is difficult. So that is one outlier.

I think you mentioned the pop-up testing sites. We are a regional site, so we are getting tests sent in from lots of other facilities. But that unknown demand can trigger on any day much more than we can handle, or it could be much less, or a very appropriate amount.

So I think having the correct supplies and the proper personnel inside the line, aligning that with the demand that we may see on any given day, does affect the timing of getting these tests back. And I think that lack of coordination, if you will, from end to end contributes to the frustration you are hearing, and the public perception about testing capabilities and confidence.

Senator PORTMAN. Rob, can you dig a little deeper in terms of the supplies? Again, I am not trying to make this about your Roche test. I am asking you more broadly about what you are experiencing, in your case in southwest Ohio. But I think many members have the same question. Is it the re-agent that is not available? And I know that depends on the test and where the re-agent comes from. I know some comes from foreign places, Germany or Asia in some cases, but what are you talking about specifically that is a bottleneck in the system in terms of supplies? And what could we do to solve that problem?

Mr. WIEHE. We have experienced shortages a little bit early on, especially on the swabs that are needed. Many of those came from one region in Europe, and that was one of the hardest hit. So that certainly created a barrier early, and it continues to be somewhat of a barrier.

But then the testing—

Senator PORTMAN. Rob, just—we have limited time here, but on the swabs, I am told that we are now making swabs in this country. Specifically we are using 3D technology and other things to try to produce them more rapidly.

Is that accurate? So do you see that problem being solved? Or is that still an issue?

Mr. WIEHE. So there has been a lot of innovation, and it is certainly not my area of expertise, per se. However, what I can tell you is, we have had 3D swabs. We have talked to laboratories. We have brought them in. As we have tested some of those innovative solutions internally, we did not feel that the results were adequate. We could not validate the results in our labs. So we have chosen not to use some of the solutions like that.

Some of the other labs, some of the other things that are being produced for other industries as well—so our lab is looking at everything. I think again, we are doing better than we did early in the crisis. Some of those innovative solutions just have not proven to be something that we at UC Health have chosen to utilize.

Again, to the solution, we are on allocation from pretty much everybody. Some of the testing products have had issues in production. And it was because of plastics or some other materials they could not get, which has severely limited what we could get.

As I mentioned earlier, hot spots. Certainly supplies are being diverted appropriately to those areas as well. So I think it is a combination of all of those factors, Senator. It is still making it a little bit of an unknown from day to day, or week to week.

Senator PORTMAN. So what I am hearing from you is that supply continues to be an issue. I will give you some homework here, if you do not mind. If you could get back to us specifically, maybe talk to some of your colleagues as well about what are the specific supplies. What could be done? The 3D technology—as we know, the FDA has gone back and forth with that, and we have to make sure

these swabs are safe and that they work well. But we also have to restore whatever we can. And if you could help us on this, the fluctuating demand issue, how could that be addressed—you know, having a bunch of pop-ups is a great idea, but if you do not have the lab capacity to get the test results quickly, maybe the pop-ups ought to be more consistent and not in need of personnel, and I am also hearing concerns there.

I have more questions for Ms. Denning—and I will get those to her—about long-term contracts. We have legislation, Ms. Denning, we are working on to try to get the Department of HHS, but also DLA—that's the Defense Logistics Agency—to consider longer-term contracts to provide the incentive for American companies to make the investments to bring back this PPE. And we would love to hear your views on that.

Thank you, Mr. Chairman.

Senator CASSIDY. Thank you, Rob. My turn now.

Ms. Denning, first, and, Dr. Grant, I am a physician, and I just want to thank all the nurses in your organization. Believe me, I just know from first-hand experience what a great service they provide. So, just thank you. I did all my practice in a public hospital for the uninsured, inner city hospitals, so just a real acknowledgment of that.

When you were asked, though, what could be done to improve the racial disparity, which is an issue we are all concerned about, you suggested—I think your reply was along the lines of further funding, research, et cetera, to address those issues.

I guess my question is, NIH has a National Institute of Minority Health and regularly puts out data and the CDC's and other Federal agencies' specific RFPs regarding addressing racial disparity. Was your reply a critique upon that? Or were you just in general endorsing it? Are you still here, Dr. Grant? I am not seeing you on the panel.

Dr. GRANT. Yes, Senator, I am still here. Yes, my reply was a little bit of both—you know, endorsing it, but also I guess you could say that it is time for action, as opposed to giving reports and having plans or recommendations that are in these reports; that we actually begin to move forward now and put our money where our mouth is, so to speak.

Senator CASSIDY. So if the research shows a specific intervention would be effective to actually attempt to implement the intervention—

Dr. GRANT. Correct.

Senator CASSIDY. So not much criticizing the amount of money or effort on the research, but just the need to implement that research. Got it.

Dr. GRANT. Yes, sir.

Senator CASSIDY. Ms. Denning, Senator Wyden suggested that most hospitals are not located where patients are who are of color, and that is a serious issue if it is true. I noticed in your self-description that of one-half of all acute-care hospitals in your system, 95 percent are academic health centers, et cetera. And it is my impression that academic health centers are often in urban areas, because that is where the patients are. And similarly, when

you think of those big hospitals in New York, they are where the patients are.

Is there that mal-distribution of hospital beds relative to people who are vulnerable, in poverty, et cetera, as Senator Wyden seemed to suggest?

Ms. DENNING. There are certainly those large academic medical centers in public hospitals that are in urban areas. If I remember what his statement was, Senator Cassidy, it was about the fact that, even though there are racial disparities in the urban areas, access to care as well as access to products is easier there than it is in the very rural areas.

Senator CASSIDY. Then let me ask you, because that goes back to your role as a GPO. Obviously GPOs, for those not familiar with them, are responsible for distributing fairly across all their members. And so I presume—I am begging the answer—but is there any preferential treatment that your GPO gives among your members as to which receive supplies?

Ms. DENNING. There is not. And in fact what we have done is, where there is a surge, because the surges are moving around the country—first we had—

Senator CASSIDY. I have limited time, so I am going to move on because I just wanted to have that point.

Mr. Wiehe, I have been told that one of the problems with hospitals being an expanded capacity for testing is that if the patient is not in your system, there is not a mechanism for the hospital to bill.

So, yes, if someone has been seen at a University of Cincinnati-affiliated hospital, or a practice affiliated, you can do it. But if you were to get a shipment from Covington, where my brother was born, and that is not part of your system, there is no billing mechanism for you to perform that service. And that somewhat limits the ability of hospitals to fill in the gap for capacity, aside from the re-agent supply, et cetera. Can you comment on that? Is that a true assessment?

Mr. WIEHE. Senator, I am—that is not my area of expertise, and I would not be able to comment on that today.

Senator CASSIDY. Could I ask you to research that?

Mr. WIEHE. Yes.

Senator CASSIDY. I would appreciate that.

Mr. JOHNSON. Mr. Chairman? Thank you, Mr. Chairman; I was hoping I would be called on. Excuse me.

Senator CASSIDY. Yes, Mr. Johnson. I really liked your comments that the supply chain sizes to the size of the market, because there have been multiple recommendations to build up manufacturing capacity, but your point is, if there is no market for the good once produced, sooner or later it becomes a stranded, useless asset. And I just want to acknowledge that.

Now with that said, you were about to make a comment otherwise. What was the comment you were going to make?

Mr. JOHNSON. Yes, I would like your indulgence to address this issue of allocation to minority and rural communities. ISEA—

Senator CASSIDY. Again, make it a quick point, because I am over time.

Mr. JOHNSON. Very quick. ISEA has bill language that would address the issue brought up by you and Senators Casey and Hassan. It would address the issue of minority and rural communities and the need for coordinated allocation and distribution by a coordinated response through FEMA and industry, and we would like to follow up with that post-hearing. Thank you.

Senator CASSIDY. That sounds great. I think Senator Wyden has an additional question he wished to ask. Is he back online? He is not. Okay, then—

Senator WYDEN. I am, Mr. Chairman—

Senator CASSIDY. Ah, Senator Wyden.

Senator WYDEN. Thank you, Mr. Chairman. I just want to make one point, because you asked the question about how in rural areas folks might acquire PPE. And as you know, I like to work with you on health-care issues whenever we can in a bipartisan way. I do not think there is any question that the example you used is of some value. I am just saying that in rural America, particularly in communities of color, there are scores and scores of hospitals and providers falling between the cracks. And that is why I gave a very real-world example I heard about from Senator Jones in Alabama.

So let us continue this dialogue, and we can work on it in a bipartisan way.

Senator CASSIDY. Sounds great. By the way, I thought you were also referencing urban, and that just was not consistent with my experience. Not to say there are not problems of access, but it is an important issue to kind of drill down on.

And let me ask one more question to you, Ms. Denning, since I am the last person. There have been calls for the Federal Government to take over the distribution of products, as if the Federal Government would be more efficient in that distribution.

You are obviously a very large GPO which distributes. Do you feel as if the supply chain currently run by the private sector would be able to manage the distribution, presuming that there was an adequate supply of that which requires distribution?

Ms. DENNING. Thank you, Senator, for the question.

We do not distribute. We have contracts for distribution. But we do have expertise in distribution, as well as contracting, for all types of products that a health-care facility would use.

That being said, I do believe that we could come together, private sector, public, the Federal Government, and work better to make sure that that strategic national stockpile is where it needs to be. And we believe that it should be utilized in times of disaster.

We do not believe that going to a totally federalized system is the answer, but we do believe working together and being able to know when we should assist the hospitals and the citizens of the United States with the products that they need to protect themselves and to protect their patients, is critically important.

Senator CASSIDY. Sounds great. Me asking you that question allowed me to find out if I am supposed to have a script to close this.

First, thank you all for participating. If members wish to submit questions for the record, there will be a period of time in which they may do so. With that, I close the hearing. Thank you very much.

[Whereupon, at 11:34 a.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF CATHY DENNING, R.N., MSN, GROUP SENIOR VICE PRESIDENT, SOURCING OPERATIONS, ANALYTICS, AND CENTER OF EXCELLENCE, VIZIENT

Good morning, Chairman Grassley, Ranking Member Wyden, and members of the committee. Thank you for holding this critically important hearing and for giving me the opportunity to testify today. My name is Cathy Denning, and I am the group senior vice president of Sourcing Operations, Analytics, and the Center of Excellence at Vizient and a registered nurse. Prior to joining Vizient 20 years ago, I practiced in the clinical arena working in both the acute care and home care settings.

Before we get started today, I'd like to tell you a little bit more about Vizient. Headquartered in Irving, TX—so if I may, I'd like to say a special “hello” to you, Senator Cornyn—Vizient is the Nation's largest member-owned, member-driven, health-care performance improvement company.

You'll hear me use the word “member” a lot today. When we say member, we mean the health-care providers that participate in our organization's services and choose to work with us every day. Vizient members include more than half of all the acute-care health-care systems, including pediatric facilities, community hospitals, integrated health delivery networks and approximately 95 percent of the Nation's academic medical centers. We also serve approximately 20 percent of the non-acute care market as well.

Most people know us for our supply chain expertise, also known as group purchasing or “GPO” expertise, which is what I will focus on today. Our group purchasing business is predicated on the idea of negotiating prices and terms and conditions for drugs, devices, and other medical products and services on behalf of our member health-care providers. In other words, we help providers realize savings and efficiencies by aggregating their purchasing volume and using that to negotiate discounts and other value, such as clinical and utilization support, with suppliers, resulting in larger savings and greater value than individual hospitals can typically negotiate on their own. Our members purchase approximately \$100 billion of goods and services off of our contracts annually.

Beyond this supply chain support, we also offer an array of consulting services, collaboration services, analytic tools, and clinical expertise—all designed to ultimately improve patient outcomes and lower the cost of health care. We see ourselves as extensions of, and advocates for, the health-care members we serve. We strive every day to be their indispensable partner—to help them achieve efficiencies, lower costs, and improve patient outcomes—with the goal of improving the health-care system for all.

Important for today's discussion, Vizient holds a unique position in that we work closely with both health-care providers and suppliers. We act as a liaison, advocating on behalf of the member providers we serve and sometimes acting as their lifeline in times of disaster.

That brings us to why we are here today—focusing on the critical issue of counterfeit PPE, the so-called “gray market” of brokers and supplies, and how at a time of grave need there were, and are, individuals and organizations looking to exploit health-care providers, the patients they serve, and the government with their false and often harmful claims of having appropriate medical supplies to offer.

But before I go into more detail regarding our experience, and our members' experiences, with counterfeit product, I think it's important that I provide some context regarding the perfect storm that led to the current situation.

First—it is my strong belief, having spent my entire career either working in a health-care setting or for a GPO, that the supply chain is not “broken” as some have claimed. We've certainly seen that there are ways that the private sector, including Vizient, can work better with other private and public sector stakeholders to make improvements—and I'll get to those later—but generally speaking, even in times of previous disasters like hurricanes, floods, and others—the health-care supply chain represents a great example of different stakeholders working together for a common purpose. Previously, manufacturers, distributors, GPOs, hospitals and others have been able to quickly put protocols and processes in place to help guide critical supplies and services to areas most in need. We are proud of the work we do on a daily basis—but surely in times of crisis.

That said—yes—when COVID-19 hit the United States, everything seemed to change overnight. And it is important to understand how the unprecedented nature of this pandemic impacted the supply chain and made it nearly impossible for anyone to fully prepare.

I realize that word—unprecedented—has been used often in describing the last several months here in the United States and across the world. But truly, this pandemic was. As you all know, the health-care industry has been looking for ways to reduce costs for more than 20 years. Lean practices to streamline clinical processes, just-in-time inventory, and tightly managing inventories of medical supplies have become more commonplace in hospitals across the country. Additionally, more manufacturing has been moved off-shore as suppliers sought to lower prices and looked for ways to achieve cost savings.

Then COVID-19 hit. No one knew how it was transmitted, where it came from, or how to treat it—only that it presented with a complicated mix of symptoms and appeared to be respiratory in nature. This meant that providers were facing an unknown, highly contagious infection and the public was panicked here and simultaneously across the globe. It was the perfect storm.

At the same time, other challenges exacerbated the problem. For example, here in the U.S. we were coming off of two spikes of influenza Type A and Type B. We were already facing critical shortages of surgical gowns due to manufacturing issues in China. Then, when COVID-19 spread across the globe, suppliers that manufacture in Asia could not get their PPE out of the country due to the sequester of those products for in-country use. In addition, although we've known for quite some time that a lack of a diverse and redundant manufacturing locations is problematic, it became acutely problematic during this crisis. To give you a specific example, the EU epicenter for COVID-19 was the Lombardy region in Italy—but that's also exactly where the overwhelming majority of the nasal swabs needed to test for COVID-19 are manufactured. While manufacturing was increased and deemed an essential business by the Italian government, it exposed a vulnerability in the supply of these critical products.

To add to the challenges, virtually overnight, hospitals were using roughly 10 times their usual amount of PPE products and those in the hardest hit areas were using 10 to 15 times their usual amount of N95 respirators at the peak of their surge. To provide context, these products are normally used only for known highly infectious respiratory illnesses during surgery and procedures that produce aerosol. Now many members are using these as universal precautions for all patients.

Bottom line—in the pre-COVID-19 environment, there was simply no way for anyone to have adequately planned for this unprecedented and ongoing spike in worldwide demand for PPE.

Which brings us to why we are here today—to expose the predatory practices of those looking to exploit this vulnerability by making false promises and offering unsafe, exorbitantly priced medical supplies to healthcare providers throughout the country, and to work together to collectively find ways to prevent these practices in the future.

One of the first things we did to help our members respond to the COVID-19 outbreak was establish a dedicated “war room” to ensure rapid responses to member needs. These dedicated staff began fielding more than 1,000 member inquiries each week. Some of these inquiries included requests to vet products that members were

considering purchasing from non-traditional manufacturers or brokers—and to provide an opinion on whether an offered product was what someone claimed it was.

The war room staff, along with our sourcing and clinical staff, and our Quality Assurance and Regulatory Affairs (QARA) professionals, quickly determined that the best way to assist our members, and have the biggest impact, would be to focus on the actual manufacturers of the products. Our QARA team has the expertise to help members understand the regulatory environment and the registration and approval requirements for manufacturers—so that is where we focused our efforts. We did not actually examine or “touch” the products themselves. We emphasized to members that our process was simply a necessary first step; if they wanted to move forward with purchasing any of these items, they would need to feel comfortable with the seller, and review samples of the products themselves to ensure the products met their internal infection control or other protocols.

Starting in mid-March, as the number of requests to vet products became more numerous, we realized that many of the requests were duplicates—either because the same broker had reached out to multiple end-points, or because multiple brokers were claiming to have product from the same original manufacturers. For example—we received 38 separate submissions purporting to be from brokers who represented a product from a single manufacturing site in China. The site *is* a legitimate manufacturer of respirators, but brokers were claiming this manufacturer could supply members with additional products including surgical masks, gloves and surgical gowns—yet we could not find any such device listings with the FDA. At least 26 brokers claimed to have access to this single manufacturer’s products. Submissions like these started in mid-March and continue to be submitted by new brokers as recently as last week.

Given these complexities, we quickly stood up a workflow management tool and database to help manage the influx of requests and to help us track where the duplications were occurring. To give you a better sense of the sheer volume—from March 29th through July 13th, we received 2,385 total requests to review products with 1,320 of these being unique requests for a unique manufacturer and product. Ultimately, we found that only 788 of these products could be validated as potentially appropriate based on the applicable FDA or NIOSH standards.

It’s important to note that this “vetted” list has morphed week after week as guidance from the Federal agencies continues to be refined. For example—the FDA issued an emergency use authorization (or EUA) for certain filtering face piece respirators on April 3rd but then, as part of their continuous quality assessment and working with the CDC and NIOSH, revised this EUA just over a month later. More than 65 filtering face piece respirators that had previously been authorized by the original EUA, many of which had appeared on our validated list, were no longer authorized. This just goes to show how complex and evolving this situation has been over the last few months—and it continues to evolve even today.

This vetting and validation process was only one piece of our overall response efforts to the pandemic. It continues to be laborious—but critical—and between these bad actors, unsafe products, demand needs of our provider members and consistent with our dedication to leaving no stone unturned to get our members what they needed, we also explored other ways to help bring more supplies to market.

Vizient has partnered with multiple suppliers to expand capacity of PPE and other vital supplies, including putting our own capital at risk with some North American suppliers to start or expand PPE manufacturing lines, thus increasing overall production capacity. Our relationship with Standard Textile, where we guaranteed purchases if they converted manufacturing lines, has helped to create more than 2 million reusable isolation gowns and more than 700,000 reusable surgical masks and face shields. With the company, Encompass, we helped to reopen their North American production line to produce 19 million level 3 disposable isolation gowns. These are just a few specific examples of how we have helped to source new product. Working with nearly a dozen more manufacturers we have helped to source Level 2 disposable gowns, nasal swabs, nitrile gloves, medical masks, and N95 sterilization processors for our healthcare provider members.

Despite our efforts, as I mentioned, counterfeit product continued—and continues—to be a problem that our provider members face. The overwhelming demand that I highlighted earlier has continued as hospitals are still facing actual or possible surges in COVID-19 cases. Although suppliers, GPOs, and the government have all taken innovative and big steps forward to meet this demand, we don’t expect that the overall supply will begin to even out until 2021. Bad actors continue

to reach out to providers in need, and our members continue to try and find whatever safe supplies they can. Unfortunately, it often times does not end well. I'd like to highlight a few specific examples of the types of situations our members have found themselves in—and, as such, bring attention to just one of the many challenges they are facing throughout this crisis.

First, our member, Yale New Haven Health in Connecticut, experienced an ongoing issue with N95 respirators. In late March they became aware that there may be counterfeit Dasheng KN95 respirators. Combing through donations they had received, they found a significant number of these counterfeit respirators. Of course, they also had open orders at the time for these Dasheng KN95s so they immediately canceled those. Yale later learned that most of the PPE vendors with whom they had been engaging were not actually dealing directly with factories in China but, rather, third party distributors or grey market brokers. Their concern around these counterfeit products led them to cancel orders they had placed directly with the Dasheng factory. Throughout this crisis, Yale discovered that many vendors had sent false test results, prompting Yale to send some of their KN95s out to a third party testing lab—turns out they were barely 85 percent efficient—leading Yale to become even more skeptical of these vendors and their product.

Second, a regional acute-care facility in Florida engaged with a broker to obtain N95 respirators supposedly manufactured by 3M. The hospital's internal review process caught that the broker was not actually licensed to sell those 3M masks so they did not contract for or end up paying for the products. They did, however, have additional purchase pending for masks but the shipments were continually delayed. Their bank got concerned that the activity was fraudulent so although they did receive some product, they canceled the remaining order and, thankfully, got their money back. But this hospital ended up losing out on two different shipments of critically needed product due to counterfeiting concerns.

Finally, one last example I'll highlight for you—but I'll note that these three examples are representative of stories we've heard from many more of our provider members. A large acute-care provider in the Pacific Northwest is currently in the middle of sorting out a questionable situation in which they were sent small-sized Halyard-manufactured N95s from a company that claimed to have sourced them in South Carolina. However, when they arrived they were in plastic bags and sealed with a sticker—not the original Halyard boxes, as would normally be expected. When this provider pressed the third-party company on this, they were told that they had a process for “reallocation” of the respirators—but would not share what this actually meant with the provider. The company in question is a sterilizer solutions firm in its normal course of business—so you can draw your own conclusions on that one—but they have been very unresponsive since our member began to question them about this incident.

As I mentioned previously—these are just three stories—there are countless other stories, and many of our members were reluctant to come forward with their stories due to reputational concerns, liability risks, or other issues. At a bare minimum, these counterfeit products and grey market brokers have taken vital resources away from our provider members and wasted hundreds of hours of time—time they could have been spending elsewhere.

In fact, some of the biggest issues our members faced throughout the country are not necessarily with respect to counterfeit product, but with gray market third parties seeking to exploit our members' needs by offering these critical products at excessive prices. Brokers, and sometimes suppliers, sought to charge hospitals \$8.50 for AAMI Level 2 and 3 non-sterile isolation gowns, when those same gowns typically go for as low as \$0.84 per gown. Similarly, brokers were trying to sell masks for as much as \$11 (with the median price being \$4.50) when they normally sell for approximately \$0.80.

Despite the contemptible actions of these bad actors and the overall challenges presented by COVID-19, I think it's important that I end my remarks today with a hopeful outlook to the future.

We are learning from our experience going through COVID-19 that vulnerabilities do exist—and therefore there are opportunities for improvement. Specifically—our supply chain needs to be more resilient, through enhanced transparency, redundancy, and diversification. We also need to take the lessons we learned regarding the strategic national stockpile and do better to ensure that it truly is a resource to States and providers.

In order to further build a resilient supply chain, more transparency is needed. Transparency into the location of manufacturing, including raw materials, as well as storage locations. And I don't just mean transparency with the FDA and other government officials—this information should be shared with private-sector partners as well so that we can aid in the diversification efforts I'm going to speak to.

Redundancy, whether it be in the PPE space or in the pharmaceutical space, where Vizient is also extremely active in helping to source product for members—we have long advocated that the best way to achieve availability and cost savings is to encourage competition. But competition is also necessary to mitigate disruption. It is critical that we have multiple manufacturers who produce the same products so that a shutdown or negative impact on one company doesn't ripple throughout the supply chain broadly.

Regarding diversification of the supply chain—I've touched on this already—but the fact that so many of our medical supplies are manufactured overseas is not the singular reason for the problems we are facing now. Similarly, onshoring all manufacturing would not solve these problems either. We need a diversified supply chain—one that is global in nature. By having multiple manufacturing locations spread across the globe, we mitigate the risk of having all manufacturing of an essential product in one location wiped out by a single event. That said, I think we can all agree that more needs to be done to create a much stronger domestic footprint.

Finally, there has been a lot of discussion regarding the Federal stockpile—we strongly believe that the stockpile does need to be bolstered and be accessible to health-care providers in need. We believe the stockpile should have at least 90 days of supplies for key items (including the essential medications list that my Vizient colleagues in pharmacy have put together—drugs without which you would be unable to provide life-sustaining care). These items, however, need to be rotated and managed as appropriate. This means that the government should continue to engage private-sector stakeholders, like Vizient, manufacturers, health-care systems and others to help provide feedback on which products should be included, how much, and how they should be stored and managed. And, again I'll emphasize the importance of transparency—which is much needed in the stockpile as well. Health-care systems and States need to be able to quickly access these products during a disaster and all participants in the supply chain need to understand the consumption of these products and overall need. That said—whether it be the Federal or State stockpiles—usage should be limited to times of emergencies, not as a regular course of business. Stockpiles are meant to supplement needs and serve a very specific, and critical purpose.

I would like to close by saying that Vizient has enjoyed a collaborative working relationship with the Federal Government and Capitol Hill for many years—but especially over these last few months. I have been pleased with how officials from FEMA, FDA, CDC, DOD, and others have been proactive in their outreach to me, our leadership team, and others throughout Vizient—and especially the outreach and support to our provider members.

With that, I want to thank you again for the opportunity to testify today. I appreciate being able to be here to share my, and Vizient's, experiences regarding counterfeit PPE products and other supply chain challenges over the last few months. As you can tell, I am passionate about these issues and strongly believe that we can all do better, working together, to help health-care providers and the patients they serve get through this crisis. I would also like to offer my sincere appreciation for all of the front line health-care workers who have given of themselves tirelessly throughout the pandemic.

I look forward to your questions.

U.S. DEPARTMENT OF HOMELAND SECURITY
Washington, DC 20472

FEMA

Voluntary Agreement

MANUFACTURE AND DISTRIBUTION OF CRITICAL HEALTHCARE RESOURCES NECESSARY TO RESPOND TO A PANDEMIC

Preface

Pursuant to section 708 of the Defense Production Act of 1950 (DPA), as amended (50 U.S.C. § 4558), the Federal Emergency Management Agency (FEMA) Administrator (Administrator), after consultation with the Secretary of the Department of Health and Human Services (HHS), the Attorney General of the United States (Attorney General), and the Chairman of the Federal Trade Commission (FTC), has developed this Voluntary Agreement (Agreement). This Agreement is intended to maximize the effectiveness of the manufacture and distribution of Critical Healthcare Resources nationwide to respond to a pandemic by establishing unity of effort between the Participants and the Federal Government for integrated coordination, planning, information sharing with FEMA, allocation and distribution of Critical Healthcare Resources. The activities contemplated by this Agreement are limited to those necessary to respond to a Pandemic, at the sole determination of FEMA. This Agreement affords Participants defenses to civil and criminal actions brought for violations of antitrust laws when carrying out this Agreement and an appropriate Plan of Action. This Agreement is intended to foster a close working relationship among FEMA, HHS, and the Participants to address national defense needs through cooperative action under the direction and supervision of FEMA. This Agreement, when implemented through a Plan of Action, affords Participants a safe harbor to exchange information, collaborate and adjust commercial operations as to particular products and services, when FEMA determines it necessary for the national defense, and only to the extent necessary for the national defense.

I. Purpose

A pandemic may present conditions that pose a direct threat to the national defense of the United States or its preparedness programs such that, pursuant to DPA section 708(c)(1), an agreement to collectively coordinate, plan and collaborate for the manufacture and distribution of personal protective equipment (PPE), Pharmaceuticals and other Critical Healthcare Resources is necessary for the national defense. This Agreement will maximize the effectiveness of the manufacture and distribution of Critical Healthcare Resources nationwide to respond to a pandemic by establishing unity of effort between the Participants and the Federal Government for integrated coordination, planning, information sharing with FEMA, allocation and distribution of Critical Healthcare Resources. The activities included in this Agreement are limited to those necessary to respond to a Pandemic, at the sole determination, direction, and supervision of FEMA and implemented through Plans of Action.

II. Authorities

Section 708, Defense Production Act (50 U.S.C. 4558); sections 402(2) and 501(b), Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121–5207); sections 503(b)(2)(B) and 504(a)(10) and (16) of the Homeland Security Act of 2002 (6 U.S.C. 313(b)(2)(B), 314(a)(10) and (16)); sections 201, 301, National Emergencies Act (50 U.S.C. 1601 et seq); section 319, Public Health Service Act (42 U.S.C. 247d); Executive Order (E.O.) 13911, 85 FR 18403 (March 27, 2020); Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use, 85 FR 20195 (April 10, 2020). Pursuant to DPA section 708(f)(1)(A), the Administrator certifies that this Agreement is necessary for the national defense.

III. General Provisions

A. Definitions

Administrator

The FEMA Administrator who, as a Presidentially appointed and Senate confirmed official, is the Sponsor of this Agreement. Pursuant to a delegation or redelegation of the functions given to the President by DPA section 708, the Administrator proposes and provides for the development and carrying out of this Agreement. The Administrator is responsible for carrying out all duties and responsibilities required by 50 U.S.C. 4558 and 44 CFR part 332 and for appointing one or more Chairpersons to manage and administer the Committee and any Sub-Committee formed to carry out this Agreement.

Agreement

The Voluntary Agreement. Participants who have been invited to join and agreed to the terms of this Agreement as described in Section VII below may join the "Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic."

Attendees

Subject matter experts, invited by the Chairperson to attend meetings authorized under this Agreement, to provide technical advice or to represent other government agencies or interested parties. Attendees are not Members of the Committee.

Chairperson

FEMA senior executive, appointed by the Administrator, to chair the "Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic." The Chairperson shall be responsible for the overall management and administration of the Committee, this Agreement, and Plans of Action developed under this Agreement while remaining under the supervision of the Administrator; may create one or more Subcommittees, as approved by the Administrator; shall initiate, or approve in advance, each meeting held to discuss problems, determine policies, recommend actions, and make decisions necessary to carry out this Agreement; and otherwise shall carry out all duties and responsibilities assigned to him. The Administrator may appoint one or more co-Chairpersons to chair the Committee and Sub-Committees, as appropriate.

Committee

Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic established under this Agreement. Provides Committee Members a forum to maximize the effectiveness of the manufacture and distribution of Critical Healthcare Resources nationwide to respond to a Pandemic through integrated coordination, planning, and identification and development of Plans of Action needed to respond to a pandemic, including making recommendations on the creation of a Plan of Action.

Critical Healthcare Resources

All categories of health and medical resources for which production and distribution capacity is necessary to respond to a pandemic, including, but not limited to, PPE, Pharmaceuticals, respiratory devices, vaccines, raw materials, supplies, and medical devices.

Documents

Any information, on paper or in electronic format, including written, recorded, and graphic materials of every kind, in the possession, custody, or control of the Participant.

Members

Collectively the Chairperson, Representatives, and Participants of the Committee. Jointly responsible for developing all decisions necessary to carry out this Agreement and to develop and execute Plans of Action under this Agreement.

Pandemic

A Pandemic is defined as an epidemic that has spread to human populations across a large geographic area that is subject to one or more declarations under the National Emergencies Act, the Public Health Service Act, or the Robert T. Stafford Disaster Relief and Emergency Assistance Act, or if the Administrator determines that one or more declarations is likely to occur and the epidemic poses a direct

threat to the national defense or its preparedness programs. For example, Coronavirus Disease 2019 (COVID–19).

Participant

An individual, partnership, corporation, association, or private organization, other than a federal agency, that has substantive capabilities, resources or expertise to carry out the purpose of this Agreement, that has been specifically invited to participate in this Agreement by the Chairperson, and that has applied and agreed to the terms of this Agreement in Section VII below. “Participant” includes a corporate or non-corporate entity entering into this Agreement and all subsidiaries and affiliates of that entity in which that entity has 50 percent or more control either by stock ownership, board majority, or otherwise. The Administrator may invite Participants to join this Agreement at any time during its effective period.

Personal Protective Equipment

Objects that provide measures of safety protection for healthcare workers, first responders, critical infrastructure personnel and/or the general public for the response to the Pandemic. These PPE items may include, but are not limited to, face coverings, filtering facepiece respirators, face shields, isolation and surgical gowns, examination and surgical gloves, suits, and foot coverings.

Pharmaceuticals

All drugs defined under the Food, Drug, and Cosmetic Act. 21 U.S.C. § 321(g), including biological products defined under the Public Health Service Act. 42 U.S.C. § 262(i).

Plan of Action

A documented method, pursuant to 50 U.S.C. 4558(b)(2), proposed by FEMA and adopted by invited Participants, to implement this Agreement, through a Sub-Committee focused on a particular Critical Healthcare Resource, or pandemic response workstream or functional area necessary for the national defense.

Plan of Action Agreement

A separate commitment made by Participants upon invitation and agreement to participate in a Plan of Action. Completing the Plan of Action Agreement confers responsibilities on the Participant consistent with those articulated in the Plan of Action and affords Participants antitrust protections for actions taken consistent with that Plan of Action as described in Section IV below.

Point of Care

All categories of medical service providers necessary to respond to a pandemic, as determined by the Chairperson after consultation with the Members of the Committee. This may include, but is not limited to, Acute Care, First Responders, Nursing Homes, Private Hospitals, Public Hospitals, Veterans Administration Hospitals, Physician Offices, Dental Offices, Ambulatory Clinics, Pharmacies, Community Health Clinics, Laboratories, and other acute and non-acute care facilities responsible for healthcare.

Representatives

The representatives the Administrator identifies and invites to the Committee from FEMA, HHS, and other federal agencies with equities in this Agreement, and empowered to speak on behalf of their agencies’ interests. The Attorney General and the Chairman of the FTC, or their delegates, may also attend any meeting as a Representative.

Sub-Committee

A body formed by the Administrator from select Participants to implement a Plan of Action.

B. Committee Participation

The Committee established under this Agreement will consist of the (1) Chairperson, (2) Representatives from FEMA, HHS, DOJ, and other federal agencies with equities in this Agreement, and (3) Participants that have substantive capabilities, resources or expertise to carry out the purpose of this Agreement. Other Attendees—invited by the Chairperson as subject matter experts to provide technical advice or to represent the interests of other government agencies or interested parties—may also participate in Committee meetings. Collectively, the Chairperson, Representatives and Participants will serve as the Members of the Committee. Public notice will be provided as each Participant joins or withdraws from this Agreement. The list of Participants will be published annually in the *Federal Register*.

C. Effective Date and Duration of Participation

This Agreement is effective immediately upon the signature of the Participant or their authorized designees. This Agreement shall remain in effect until terminated in accordance with 44 CFR 332.4, or in any case, it shall be effective no more than five (5) years from the date the requirements of DPA section 708(f)(1) are satisfied as to the initial Voluntary Agreement regarding the manufacture and distribution of critical healthcare resources necessary to respond to a Pandemic, unless otherwise terminated pursuant to DPA section 708(h)(9) and 44 CFR 332.4 or extended as set forth in DPA section 708(f)(2). No action may take place under this Agreement until it is activated, as described in Section III(E.), below.

D. Withdrawal

Participants may withdraw from this Agreement at any point, subject to the fulfillment of obligations incurred under this Agreement prior to the date this agreement is terminated with regard to such Participant, by giving written notice to the Administrator at least fifteen (15) calendar days prior to the effective date of that Participant's withdrawal. Following receipt of such notice, the Administrator will inform the other Participants of the date of the withdrawal. Upon the effective date of the withdrawal, the Participant must cease all activities under this Agreement.

E. Plan of Action Activation and Deactivation

Upon occurrence of a Pandemic, the Administrator may authorize a Plan of Action and Sub-Committee for one or more specific Pandemic response workstreams, functional areas, or Critical Healthcare Resource national defense needs, *e.g.*, a pharmaceuticals plan of action, or a PPE distribution plan of action, or a vaccine plan of action. The Administrator will invite a select group of Participants who are representative of the segment of the industry for which the Plan of Action is intended to participate on the Sub-Committee. The Plan of Action will be activated for each invited Participant when the Participant executes a Plan of Action Agreement. Actions taken by Participants to develop a Plan of Action and actions taken after executing a Plan of Action Agreement to collectively coordinate, plan and collaborate, pursuant to that Plan of Action and as directed and supervised by FEMA, will constitute action taken to develop and carry out this Agreement pursuant to 50 U.S.C. 4558(j).

Sub-Committees will meet only for the purposes specified in this Agreement and as provided for in writing by the Chairperson. They will report directly to the Committee regarding all actions taken by them, and any Plan of Action adopted by a Sub-Committee must be approved first by the Chairperson. A Plan of Action may not become effective unless and until the Attorney General (after consultation with the Chairman of the Federal Trade Commission) finds, in writing, that such purpose(s) of the Plan of Action may not reasonably be achieved through a Plan of Action having less anticompetitive effects or without any Plan of Action and publishes such finding in the *Federal Register*. The Chairperson may appoint a Sub-Committee Chairperson to preside over each Sub-Committee as a delegate of the Chairperson; however, the Chairperson retains responsibility for all Sub-Committees and for administrative and record keeping requirements of any meetings held by such Sub-Committees, including providing public notice as required of any meetings.

When recommended by the Sub-Committee Chairperson, the Administrator will provide notice of a Plan of Action Deactivation. Any actions taken by Participants after the Deactivation date are outside the scope of Plan of Action Agreement and the Section IV antitrust defense is not available.

F. Rules and Regulations

Participants acknowledge and agree to comply with all provisions of DPA section 708, as amended, and regulations related thereto which are promulgated by FEMA, the Department of Homeland Security, HHS, the Attorney General, and the FTC. FEMA has promulgated standards and procedures pertaining to voluntary agreements in 44 CFR part 332. The Administrator shall inform Participants of new rules and regulations as they are issued.

G. Modification and Amendment

The Administrator, after consultation with the Attorney General and the Chairman of the FTC, may terminate or modify, in writing, this Agreement or a Plan of Action at any time, and may remove Participants from this Agreement or a Plan of Action at any time. Participants may propose modifications or amendments to this Agreement at any time. The Administrator shall inform Participants of modifications or amendments to this Agreement as they are issued. If a Participant indicates an intent to withdraw from the Agreement due to a modification or amend-

ment of the Agreement, the Participant will not be required to perform actions directed by that modification or amendment.

The Attorney General, after consultation with the Chairman of the FTC and the Administrator, may terminate or modify, in writing, this Agreement or a Plan of Action at any time, and may remove Participants from this Agreement or a Plan of Action at any time. If the Attorney General decides to use this authority, the Attorney General will notify the Chairperson as soon as possible, who will in turn notify Participants.

H. Expenses

Participation in this Agreement does not confer funds to Participants, nor does it limit or prohibit any pre-existing source of funds. Unless otherwise specified, all expenses, administrative or otherwise, incurred by Participants associated with participation in this Agreement shall be borne exclusively by the Participants.

I. Record Keeping

The Chairperson shall have primary responsibility for maintaining records in accordance with 44 CFR part 332, and shall be the official custodian of records related to carrying out this Agreement. Each Participant shall maintain for five years all minutes of meetings, transcripts, records, documents, and other data, including any communications with other Participants or with any other member of the Committee, including drafts, related to the carrying out of this Agreement or any Plan of Action or incorporating data or information received in the course of carrying out this Agreement or any Plan of Action. Each Participant agrees to produce to the Administrator, the Attorney General, and the Chairman of the FTC upon request any item that this section requires the Participant to maintain. Any record maintained in accordance with 44 CFR part 332 shall be available for public inspection and copying, unless exempted on the grounds specified in 5 U.S.C. 552(b)(1), (3) or (4) or identified as privileged and confidential information in accordance with DPA section 705(d), and 44 CFR 332.5.

IV. Antitrust Defense

Under the provisions of DPA subsection 708(j), each Participant in this Agreement shall have available as a defense to any civil or criminal action brought for violation of the antitrust laws (or any similar law of any State) with respect to any action to develop or carry out this Agreement or a Plan of Action, that such action was taken by the Participant in the course of developing or carrying out this Agreement or a Plan of Action, that the Participant complied with the provisions of DPA section 708 and the rules promulgated thereunder, and that the Participant acted in accordance with the terms of this Agreement and any relevant Plan of Action. Except in the case of actions taken to develop this Agreement or a Plan of Action, this defense shall be available only to the extent the Participant asserting the defense demonstrates that the action was specified in, or was within the scope of, this Agreement or a Plan of Action.

This defense shall not apply to any action occurring after the termination of this Agreement or a Plan of Action. Immediately upon modification of this Agreement or a Plan of Action, no antitrust immunity shall apply to any subsequent action that is beyond the scope of the modified Agreement or Plan of Action. The Participant asserting the defense bears the burden of proof to establish the elements of the defense. The defense shall not be available if the person against whom the defense is asserted shows that the action was taken for the purpose of violating the antitrust laws.

V. Terms and Conditions

Each Participant agrees to voluntarily collaborate with all Committee Members to recommend Plans of Action and Sub-Committees that will, at the direction of and under the supervision of FEMA, maximize the effectiveness of the manufacture and distribution of Critical Healthcare Resources nationwide to respond to a pandemic by establishing unity of effort between the Participants and the Federal Government for integrated coordination, planning, information sharing with FEMA, and allocation and distribution of Critical Healthcare Resources. These efforts aim to promote efficiency and timeliness to mitigate shortages of Critical Healthcare Resources to respond to a Pandemic and to meet the overall demands of the healthcare

and other selected critical infrastructure sectors, along with those demands necessary to continue all-level-of-government mission-essential functions.

As the sponsoring agency, FEMA will maintain oversight over Committee and Sub-Committee activities and direct and supervise actions taken to carry out this Agreement and subsequent Plans of Action, including by retaining decision-making authority over actions taken pursuant to this Agreement and subsequent Plans of Action to ensure such actions are necessary to address a direct threat to the national defense. The Department of Justice (DOJ) and the Chairman of the FTC will monitor activities of the Committee and Subcommittees to ensure they execute their responsibilities in a manner consistent with this Agreement having the least anti-competitive effects possible.

A. Plan of Action Execution

Specific Member obligations and actions to be undertaken will only be provided for in individual Plans of Action, not in the Agreement. Activities taken to develop a Plan of Action or to implement a Plan of Action that has been activated pursuant to section III.E. above will provide Participants the antitrust defense described in section IV. Each Plan of Action will endeavor to clearly identify the conduct that Participants will undertake in carrying out the Plan of Action and that would be subject to the defense described in Section IV.

Each Plan of Action will describe what information Members will share, as directed by FEMA and under FEMA's supervision. Information will be used to create a common operating picture in furtherance of the Plan of Action's purpose and/or to promote overall situational awareness of Critical Healthcare Resource manufacturing and distribution activities.

Each Plan of Action, and information gathered pursuant to that plan, will be used to support one or more of the following objectives:

- (1) Facilitate maximum availability of Critical Healthcare Resources to end-users by deconflicting overlapping requirements for the collective Participant customer base;
- (2) Facilitate maximum availability of Critical Healthcare Resources to Members by deconflicting overlapping supply chain demands of Members;
- (3) Facilitate efficient distribution of Critical Healthcare Resources by deconflicting overlapping distribution chain activities of Members;
- (4) Inform where expansion of the manufacture of Critical Healthcare resources is necessary;
- (5) Identify and prioritize Critical Healthcare Resource requirements;
- (6) Validate Critical Healthcare Resource requirements;
- (7) Project future demand for Critical Healthcare Resource requirements.
- (8) Execute a collaborative manufacturing strategy to more efficiently make use of limited resources for key manufacturing lines of effort for Critical Healthcare Resources;
- (9) Collaborate in the voluntary Participant allocation of Critical Healthcare Resources nationwide;
- (10) Cooperate to the fullest extent possible to distribute Critical Healthcare Resources to locations most in need, as identified by FEMA;
- (11) Explore strategies for increased manufacturing of Critical Health Resources in or near the United States;
- (12) Carry out any other activities as determined and directed by FEMA necessary to address the Pandemic's direct threat to the national defense.

B. Information Management and Responsibilities

FEMA will request only that data and information from Participants that is necessary to meet the objectives of a Plan of Action. Upon signing a Plan of Action Agreement, participants should endeavor to cooperate to the greatest extent possible to share data and information necessary to meet the objectives of the Plan of Action.

The specific data requested, procedures for sharing that data, and data management and disposition will be tailored for each specific Plan of Action. Where feasible and to the greatest extent possible, FEMA will incorporate the following principles regarding data sharing into each Plan of Action:

- In general, Participants will not be asked to share competitively sensitive information directly with other Participants. Direct sharing of information among Participants will be requested only when necessary and will be closely supervised by FEMA, including requiring appropriate safeguards regarding participant use and dissemination of other participants' data.

- If FEMA needs to share information with parties outside the Sub-Committee, FEMA will limit the amount and type of information shared to the greatest extent feasible and permitted by law, while still furthering the objectives of the Plan of Action.
- Prior to distribution within or outside the Sub-Committee, FEMA will aggregate and anonymize data in such a way that will maximize the effectiveness of the Plan of Action without compromising competitively sensitive information.
- Pursuant to 5 U.S.C. 552(b)(4) and 44 CFR 332.5, FEMA will withhold from disclosure under the Freedom of Information Act Participant trade secrets and commercial or financial information and will restrict Sub-Committee meeting attendance where necessary to protect trade secrets and commercial or financial information.
- Any party receiving competitively sensitive information through a Plan of Action shall use such information solely for the purposes outlined in the Plan of Action and take steps, such as imposing firewalls or tracking usage, to ensure such information is not used for any other purpose. Disclosure and use of competitively sensitive information will be limited to the greatest extent possible.
- At the conclusion of a Participant's involvement in a Plan of Action—due to the deactivation of the Plan of Action or due to the Participant's withdrawal or removal—each Participant will be requested to sequester any and all competitively sensitive information received through participation in the Plan of Action. This sequestration will include the deletion of all competitively sensitive information unless required to be kept pursuant to the Record Keeping requirements as described *supra*, Section I, 44 CFR part 332, or any other provision of law.

C. Oversight

The Chairperson is responsible for ensuring the Attorney General, or suitable delegate(s) from the DOJ, and the FTC Chairman, or suitable delegate(s) from the FTC, have awareness of activities under this Agreement, including Plan of Action activation, deactivation, and scheduling of meetings. The Attorney General, the FTC Chairman, or their delegates may attend Committee and Sub-Committee meetings and request to be apprised of any activities taken in accordance with activities under this Agreement or a Plan of Action. DOJ or FTC Representatives may request and review any proposed action by the Committee, Sub-Committee or Participants undertaken pursuant to this Agreement or Plan of Action, including the provision of data. If any DOJ or FTC Representative believes any actions proposed or taken are not consistent with relevant antitrust protections provided by the DPA, he or she shall provide warning and guidance to the Committee as soon as the potential issue is identified. If questions arise about the antitrust protections applicable to any particular action, FEMA may request DOJ, in consultation with the FTC, provide an opinion on the legality of the action under relevant DPA antitrust protections.

VI. Establishment of the Committee

There is established a Committee for the Manufacture and Distribution of Healthcare Resources Necessary to Respond to a Pandemic (Committee) to provide the Federal Government and the Participants a forum to maximize the effectiveness of the manufacture and distribution of Critical Healthcare Resources nationwide to respond to a Pandemic through integrated coordination, planning, and information sharing with FEMA. A Chairperson designated by the FEMA Administrator will convene and preside over the Committee. The Committee will not be used for widespread or collective exchange of information among members. These activities, if required, shall be done within individual Sub-Committees, and in accordance with an established Plan of Action. The Committee will not be used for contract negotiations or contract discussions between the Participants and the Federal Government; such negotiations or discussions will be in accordance with applicable federal contracting policies and procedures. However, this shall not limit any discussion within a Sub-Committee about the operational utilization of existing and potential contracts between the Participants and Representatives when seeking to align their use with overall manufacturing and distribution efforts consistent with this Agreement and a Plan of Action.

The Committee will consist of designated Representatives from FEMA, HHS, other federal agencies with equities in this Agreement, and each Participant. The

Attorney General and Chairman of the FTC, or their delegates, may also join the Committee and attend meetings at their discretion. Attendees may also be invited at the discretion of the Chairperson as subject matter experts, to provide technical advice, or to represent other government agencies, but will not be considered part of the Committee.

To the extent necessary to respond to the Pandemic and at the explicit direction of the Chairperson, the Committee Members will provide technical advice to each other as needed, share information collectively, identify and validate places and resources of the greatest need, project future manufacturing and distribution demands, collectively identify and resolve the allocation of scarce resources amongst all necessary public and private sector domestic needs, and as necessary, share vendor, manufacturer and distribution information, and take any other necessary actions to maximize the timely manufacture and distribution of Critical Healthcare Resources as determined necessary by FEMA to respond to the Pandemic. The Chairperson or his or her designee, at the Chairperson's sole discretion, will make decisions on these issues in order to ensure the maximum coordination, efficiency, and effectiveness in the use of Member's resources and will create and execute Plans of Action as needed. All Participants will be invited to open Committee meetings. For selected Committee meetings, attendance may be limited to designated Participants to meet specific operational requirements.

The Committee Chairperson shall notify the Attorney General, the Chairman of the FTC, Representatives, and Participants of the time, place, and nature of each meeting and of the proposed agenda of each meeting to be held to carry out this Agreement. Additionally, the Chairperson shall provide for publication in the *Federal Register* of a notice of the time, place, and nature of each meeting. If a meeting is open, a *Federal Register* notice will be published reasonably in advance of the meeting. The Chairman may restrict attendance at meetings only on the grounds outlined by 44 CFR 332.5(c)(1)–(3). If a meeting is closed, a *Federal Register* notice will be published within 10 days of the meeting and will include the reasons why the meeting is closed pursuant to 44 CFR 332.3(c)(2).

The Chairperson shall establish the agenda for each meeting, be responsible for adherence to the agenda, and provide for a written summary or other record of each meeting and provide copies of transcripts or other records to FEMA, the Attorney General, the Chairman of the FTC, and all Participants. The Chair shall take necessary actions to protect from public disclosure any data discussed with or obtained from Participants which a Participant has identified as a trade secret or as privileged and confidential in accordance with DPA sections 708(h)(3) and 705(d), or which qualifies for withholding under 44 CFR 332.5.

The Administrator, in his or her sole discretion and after consultation with the Committee Members, will create Plans of Action and Sub-Committees for specific workstreams or functional areas requiring collective coordination, planning, and collaboration. These Sub-Committees shall be subject to the same rules, regulations and requirements of the Committee and any other rules or requirements deemed necessary by the Chairperson, the Administrator, or the Attorney General, after consultation with the Chairman of the FTC.

VII. Application and Agreement

The Participant identified below hereby agrees to join in the Federal Emergency Management Agency sponsored Voluntary Agreement entitled Committee for the Manufacture and Distribution of Healthcare Resources Necessary to Respond to a Pandemic (Agreement) and to become a Participant in this Committee. This Agreement will be published in the *Federal Register*. This Agreement is authorized under section 708 of the Defense Production Act of 1950, as amended. Regulations governing this Agreement appear at 44 CFR part 332. The applicant, as Participant, agrees to comply with the provisions of section 708 of the Defense Production Act of 1950, as amended, the regulations at 44 CFR part 332, and the terms of this Agreement.

VIII. Assignment

No Participant may assign or transfer this Agreement, in whole or in part, or any protections, rights or obligations hereunder without the prior written consent of the

Chairperson. When requested, the Chairperson will respond to written requests for consent within 10 business days of receipt.

Vizient, Inc.

Primary Contact: Steve Downey (stephen.downey@vizientinc.com)

Secondary Contact: Shohana Krilow (shoshana.krilow@vizientinc.com)

10/8/2020

QUESTIONS SUBMITTED FOR THE RECORD TO CATHY DENNING, R.N., MSN

QUESTIONS SUBMITTED BY HON. RON WYDEN

Question. You noted during your testimony that during a normal year, 15 million N95 masks are used, and that so far this year, 500 million N95 masks have been used. Please provide data on other categories of PPE, including but not limited to, surgical masks, face shields, gloves, isolation gowns, hand sanitizer? Which supply categories are currently experiencing shortages (please quantify or provide specific examples), and which categories cause you the most concern about shortages moving forward?

Answer. First—to clarify a critical point—the 500 million N95 number I provided references the number of masks we estimate our members ordered, but not necessarily the number that were received or shipped. This number reflects a significant demand increase but it's important to clarify that hospitals did not likely receive all of the items they attempted to purchase. **Regarding your question about data on other categories of PPE, please find a table at the end of the document that shows the increase in volume of orders received between 2019 and 2020.**

With respect to PPE, the market does seem to have softened around hand sanitizer, surgical masks, face shields and isolation gowns. For the time being our members seem to be able to obtain adequate products through their current suppliers for their daily needs. In addition, many providers have invested in building reserves of these products where feasible. For some products, like N95s, members report that they have continued with extended use and reprocessing for these products and when the supply is completely healthy, they will return to supplying these daily as needed. This level of having adequate supply could shift if there is a repeat of supply constraints like earlier in the year with the two waves of influenza and the emergence of COVID-19.

The exam glove market, however, is experiencing unprecedented demand increases in both health-care and non-health-care settings. This increased demand is being driven by stockpile buying (in some cases to meet State and local government standards), as well as increased buying from the non-health-care sector and buying from outside of the US. This increase in demand is exacerbated by a lack of excess capacity or ability to quickly expand within glove manufacturers, the significant cost and technological barriers to entry into the glove manufacturing market, as well as the barring of some large glove manufacturers from shipping to the U.S.

This, in turn, has led to astronomical pricing increases. Prior to the pandemic, hospitals were able to purchase gloves at an average cost of \$.03–\$.04 per glove; we are now seeing hospitals pay more than \$.105 with some manufacturers and distributors predicting \$.15 average pricing in the 4th quarter with further price increases expected in early 2021.

These price increases have been driven, up until now, primarily by increased worldwide demand and profit-taking by manufacturers. However, manufacturers are now reporting a 25-percent increase in raw materials which will further drive pricing on gloves delivered in November and December.

As with glove manufacturing, the raw materials companies exist almost exclusively within China and Southeast Asia. As glove manufacturers are investing in expansion of production, a significant question will be whether or not the raw materials makers have the capacity to supply new manufacturing capabilities.

For hand sanitizers, the market share leaders (GOJO, Ecolab) are still on distribution allocation (average is 150 percent) but there are not any issues hitting the allocation.

Question. In a statement for the record, Premier, Inc., which operates similar businesses to Vizient, called for “real-time syndromic surveillance to provide an upstream alternative to identifying cases before tests can detect them or patients are hospitalized.” From your company’s point of view how could such a system augment existing disease surveillance efforts? Similarly, can PPE demand data be used to inform understanding of where COVID–19 outbreaks are occurring?

Answer. Vizient’s approach is upstream to real-time syndromic surveillance. The challenge with surveillance is that by the time a person is presenting with symptoms, the infection has likely already spread. We believe that surveillance can be limited as leading factor. Based on what we know about the disease, coupled with modeling social distancing patterns, population density and vulnerable patient populations, we actually have insights prior a patient presenting to the health system as symptomatic. Vizient harnesses these factors, along with previous infection rate patterns, to gain insight into future COVID–19 burdens prior to any “real-time” syndromic surveillance indications. Vizient has developed statistical forecasts of COVID infection rates that provide future demand not only at the individual hospital level, but also at the city, State and national levels. This can help us and our members assess future hospitalizations, including ICU utilization, as well as future PPE demand. Vizient is actively leveraging these insights to proactively work with our membership to assess and plan for future resource needs.

Question. What, if any, data is or has Vizient been sharing with the Supply Chain Task Force and/or FEMA?

Answer. Vizient holds regular calls with FEMA and others in the administration to share information related to demand data, fill rates, member concerns, and other issues related to the supply chain. This also includes item lists such as reference information from our product data including what specific items are within a category (e.g., part numbers of gowns). We have also shared master reference data such as catalog data listing—a given item number and what each of the distributors use as item numbers for those items and their different units of measure. On the pharmaceutical side, we have shared the following information, some of which was sent to an organization called Healthcare Ready for them to share directly with FEMA or other government officials:

- April 4, 2020—Listing of top generic drug manufacturers contact information sent to Healthcare Ready.
- April 7, 2020—FEMA ICU patient drugs—added missing drugs, amended dosing recommendations and supply size needed for COVID treatment sent to Healthcare Ready.
- April 7, 2020—COVID drug list for FDA—COVID drugs and corresponding fill rates sent to Healthcare Ready.
- April 8, 2020—COVID drug list for FDA—updated with additional tab providing crosswalk information for each drug being monitored to assist FEMA sent to Healthcare Ready.
- April 22, 2020—Vizient report to FDA and COVID–19 impact upon ventilator drugs—demand and fill rate for 48 drugs being tracked for FDA along with a weekly analysis presented in PPT on ventilator drugs sent to Healthcare Ready.
- April 27, 2020—Common COVID ventilator medications—Vizient fulfilled request for information on common drugs expected to be used in management of ventilated patients sent to Healthcare Ready.
- April 28, 2020—Supply Chain Task Force primary and secondary medications priorities—Vizient reviewed and provided feedback on a draft list of priority medications the FEMA Supply Chain Task Force plans to track sent to Healthcare Ready.
- May 1, 2020—Fill rate tracker FEMA—Vizient responded to FEMA request for fill rates across 15 specific vent meds sent to Healthcare Ready.
- May 2, 2020—Fill rate tracker FEMA—Vizient provided an update and responded to methodology question supporting detail on how fill rates are calculated sent to Healthcare Ready.
- May 7, 2020—GPO site usage for 15 ventilator medications—responded to request to expand fill rate to include total utilization (demand) by month across GPO membership sent to Healthcare Ready.
- May 7, 2020—Remdesivir requests—shared additional feedback with FEMA in response to distribution limitations of Remdesivir across many of our member hospitals sent to Healthcare Ready—this was done every business day until a more formal process for Remdesivir distribution was laid out by HHS.

Question. Please provide copies of any agreements that Vizient has signed with the task force or FEMA.

Answer. As of October 8, 2020, Vizient has signed a Voluntary Agreement with FEMA pursuant to the Defense Production Act. A copy of that agreement is included as a separate attachment (see p. 44).

Question. My State of Oregon relied upon an Emergency Use Authorization issued by the Food and Drug Administration as a stamp of quality when it acquired N95 respirators, only to have that decision reversed after the State imported them from China. The U.S. agency that actually tests and certifies these respirators—NIOSH—now says that Chinese manufacturers are telling them some of the respirators they de-certified were counterfeit. In a recent article, *The Wall Street Journal* attempted to quantify the problem that States across the country faced (“FDA’s Shifting Standards for Chinese Face Masks Fuel Confusion,” August 3, 2020), reporting that State agencies submitted orders for more than 180 million KN95 masks that “are now sitting unwanted in warehouses due to quality concerns,” and that “more than 60 percent of foreign-made masks, nearly all Chinese made, have failed basic U.S. government quality tests that looked at 220 such brands.” Please answer the following:

Were counterfeit, fraudulent or otherwise substandard PPE a significant problem for the U.S. prior to this pandemic?

Answer. No.

Question. Is this primarily driven by the massive surge in demand for PPE?

Answer. Yes.

Question. Has the FDA’s decision to list and delist KN95 masks complicated efforts to obtain sufficient supplies of respirators?

Answer. Yes. While the various EUAs have been appreciated, the addition of multiple products labeled as KN95, coupled with these products being easily counterfeited, created a problem for providers. Providers subsequently purchased these products before the EUAs were rescinded which then led to them being ultimately unusable. All of this complicated the overall efforts to obtain sufficient supply of usable N95s.

Question. Would your members have benefited from more Federal leadership throughout this pandemic procuring quality safety equipment?

Answer. We have appreciated working with individuals throughout the administration on this critical issue. All stakeholders, including the government, could have improved in their overall response to COVID–19, and we look forward to continuing to engage as we all work towards the same goals.

Question. The Trump administration testified in July that it has used the Defense Production Act “more than 10 times” to combat COVID–19, an extraordinarily narrow use of existing authority that stands in stark contrast to Federal agencies’ historical use of DPA. Historically, the statute’s authority has been used to acquire supplies and services in times of emergency and in day-to-day business. For example, the Department of Defense places approximately 300,000 rated orders annually, while the Department of Homeland Security, including FEMA, placed more than 1,000 rated orders and contracts in 2018. Specific examples include using priority orders to acquire the Adenovirus vaccine, expediting construction of floodwater controls in New Orleans, speeding up the purchase of railroad equipment following Hurricane Katrina, and obtaining resources needed to house and feed disaster survivors and first responders, communications equipment and information technology needs, and other logistical needs supporting disaster response and recovery efforts. Given the shortages of PPE you have experienced, shouldn’t the administration use the Defense Production Act to increase the availability of personal protective equipment and better allocate supplies?

Answer. We have previously stated our support for—and continue to support—the use of the DPA and other means to increase the supply of PPE and other critical products.

Question. The Trump administration has relied on the practice of reusing PPE to make it look like there are adequate supplies at hospitals and other medical settings, which has been a big safety concern for workers. The American Nurses Association surveyed 14,000 nurses in May and found that 45 percent worked at facilities with shortages of PPE, and 79 percent reported having to reuse PPE. In July, the National Nurses Union released a survey of 21,000 nurses, of which 87 percent

reported re-using PPE. My staff heard similar stories from around the country. One nurse in Houston, where the virus is surging, told Minority staff that her hospital is cleaning and reusing N95 masks up to 10 times. Ms. Denning, if your members were not reusing PPE intended for single use, would there be more severe shortages of supplies?

Answer. Yes.

QUESTION SUBMITTED BY HON. DEBBIE STABENOW

Question. As we continue to respond to this pandemic, we also know that influenza season will soon start. You mention in your written testimony that a spike in influenza cases just prior to the pandemic had hindered our PPE supply. Do you have similar concerns about the upcoming flu season?

Answer. Yes.

QUESTION SUBMITTED BY HON. SHELDON WHITEHOUSE

Question. Like many States, Rhode Island has had chilling experiences procuring PPE, including unfulfilled orders, fraudulent sales, and a competitive race for supplies. This toxic atmosphere discourages not only buyers, but also suppliers, from entering the PPE market, as manufacturers face challenges understanding the market, product standards, and the allocation process. In your experience as buyers of PPE on behalf of hospitals and health-care providers, what does the current PPE market look like and how has it been tainted by the disorganized, toxic procurement process?

Answer. First—to clarify the role of a GPO—we do not take title to products (or buy products). Our primary role is to leverage the scale of our membership to negotiate prices on their behalf for goods and services. That said, as I mentioned in my testimony, there have been many bad actors who have looked to exploit health-care providers, patients, and the government by preying on the critical need for PPE and other products.

Additionally, in recent years, hospitals have been driven to the lowest cost item and a just-in-time inventory system to keep supply costs as low as possible. However, because of this approach to managing a challenging financial environment, many health-care systems found themselves unprepared for the unprecedented volume of COVID-19 patients.

We believe the PPE market has been adversely impacted in that traditional, quality suppliers looking to grow their capacity to help meet the increased needs were, in turn, met with factories in other countries that saw an opportunity to significantly increase prices and sell dedicated manufacturing lines to the highest bidder. We also experienced an emergence of third-party brokers (many questionable) that were securing product in other countries and didn't have the expertise to validate the manufacturer, evaluate the product quality or appreciate the required certifications needed for U.S.-based health-care providers.

That being said, there have been some positive outcomes that include increased demand for transparency around origin of manufacturing and raw materials, PPE innovation and overall competition. We experienced innovative approaches to a number of PPE categories including gowns, masks and face shields. We have also seen new market entrants into the healthcare market.

This experience underscored the importance of the terms and conditions of GPO contracts that include failure to supply, warranty, competitive pricing, validated quality as well as governmental regulations.

QUESTION SUBMITTED BY HON. SHERROD BROWN

Question. In your testimony, you acknowledged that supply chain vulnerabilities exist, and in order to improve our supply chain and make it more resilient we must increase transparency, redundancy, and diversification. Can you provide specific suggestions for how the U.S. government, particularly through the strategic national stockpile and other Federal programs focused on preparedness and response, can increase transparency, redundancy, and diversification within our PPE supply chain?

Answer. Location of manufacturing. Require the physical address of the most significant manufacturing steps to be available to the public, as well as other manufacturing steps or contract manufacturing.

Location of raw materials. Require the physical address of each raw material supplier be supplied and available to the public.

Supply capacity. Require manufacturers to disclose capacity of each manufacturing location, by product sku, with current capacity and potential expansion capacity.

Share information on demand, stock, and supply. As the government builds databases about the health of supply chains, through demand, on-hand inventory and supply information, make that information available to industry participants, including GPOs.

SNS. As health systems consume product within State/Federal stockpiles, provide a report to industry stakeholders, including the GPOs that serve those hospitals, for enhanced visibility. Also inform GPOs of the products and stock levels within the SNS so we can assess the risks to supply.

Local supply. Help drive a more resilient supply chain by investing in domestic supply of manufacturing.

QUESTION SUBMITTED BY HON. CHUCK GRASSLEY

Question. We've heard from some manufacturers and suppliers that increased transparency within the supply chain could harm competition and expose confidential business information. Can you respond to these concerns? How can the Federal Government increase transparency while balancing these concerns?

Answer. Yes, we have also heard the argument that increased transparency of manufacturing information is not possible due to the risk of disclosing confidential details and/or creating a less competitive marketplace. In response, we must note that the existing environment of limited or non-existent information regarding the manufacturing quality or the origination of source of active pharmaceutical ingredients and other medication components has failed to deliver the resilient and safe supply channel that is required to sustain patient care. For example, in addition to the recent pandemic, drug shortages cost the U.S. health-care system at least \$360 million annually. The concept of increased disclosure and transparency regarding manufacturing and quality has been articulated in the Food and Drug Administration's task force on drug shortages and championed by numerous other organizations including the American Hospital Association, the American Medical Association, the United States Pharmacopeia, the American Society of Health-System Pharmacists, and Vizient.

The expectation for increased transparency is no longer a negotiable situation. Too many stakeholders now expect this level of clarity and are taking steps to gather information to make more informed sourcing decisions. We would strongly encourage the pharmaceutical and medical device industries to support this endeavor and ensure end users have accurate information on which to make their decisions. Furthermore, we fully anticipate that those companies who volunteer information and demonstrate a visible and documented commitment to quality will be even more competitive as compared to those who resist this transformation. We similarly urge the government, through congressional or other action, to hold manufacturers accountable for this level of needed transparency.

FOLLOW-UP FROM QUESTION 1:

2019 vs. 2020 Submitted Invoice Volume

PPE Categories	2019 Est. U.S. Acute Care Invoice Volume (Based on Jan-Jul annualized Vizient Member Spend)	2020 Est. U.S. Acute Care Invoice Volume (Based on Jan-Jul annualized Vizient Member Spend)	Invoiced Volume Increase	Order Volume Increase
Face Shields	331,760	1,191,431	259%	690% at peak
Exam Gloves	22,480,253,366	27,338,294,843	22%	260% at peak

2019 vs. 2020 Submitted Invoice Volume—Continued

PPE Categories	2019 Est. U.S. Acute Care Invoice Volume (Based on Jan–Jul annualized Vizient Member Spend)	2020 Est. U.S. Acute Care Invoice Volume (Based on Jan–Jul annualized Vizient Member Spend)	Invoiced Volume Increase	Order Volume Increase
Isolation Gowns	539,918,064	847,360,528	57%	380% at peak
N95 Respirators	29,761,566	121,847,624	309%	4,000% at peak
Surgical Masks (tie behind)	145,291,499	239,105,409	65%	650% at peak
Procedure Masks (ear loop/elastic)	529,432,461	1,452,702,635	174%	650% at peak
Shoe Covers	193,979,281	231,508,380	19%	

Invoiced Volume in Eaches

Assumptions:

- Estimated U.S. Acute Care volumes are built on invoice data shared with Vizient from member hospitals and based on the following:
The data provided represent 80 percent of the total Vizient member volume
Vizient members represent ~50 percent of the U.S. Acute Care market volume
- Invoice volume reflects the actual quantities that were shipped in comparison to order volumes which can be overstated due to hospital and distributor ordering practices
- Order quantity perspective provided by Owens and Minor to Vizient
- Includes all safety levels

PREPARED STATEMENT OF ERNEST GRANT, PH.D., R.N., FAAN,
PRESIDENT, AMERICAN NURSES ASSOCIATION

Chairman Grassley, Ranking Member Wyden, and members of the committee, thank you for giving me the opportunity to appear before you, on behalf of the American Nurses Association (ANA), to discuss the need to protect the reliability of the United States medical supply chain during the COVID-19 pandemic. Nurses and other health-care providers in communities across the country have been on the front lines of the coronavirus pandemic and have been negatively impacted by the shortages of Personal Protective Equipment (PPE) caused by the global impact of COVID-19.

ANA is the premier organization representing the interests of the Nation's over 4 million registered nurses (RNs), through its State and constituent member associations, organizational affiliates, and individual members. ANA members also include the four advanced practice registered nurse roles (APRNs): nurse practitioners (NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs) and certified registered nurse anesthetists (CRNAs). ANA is dedicated to partnering with health-care consumers to improve practices, policies, delivery models, outcomes, and access across the health-care continuum.

This is one of the most difficult times nurses have ever faced. At the beginning of this crisis the United States saw nurses and other front-line health-care professionals confronting a shortage of personal protective equipment by making their own masks or using trash bags for make-shift gowns. Because of the unsafe working conditions, some made the difficult choice to leave their jobs to protect their families and themselves. Others developed emotional and psychological issues, suffered severe physical ailments from the coronavirus and tragically, all too many, more than 230 nurses died providing care to their communities. This is unacceptable.

Nurses must be protected and supported so they can continue to care for patients and educate the public. We must safeguard nurses' and other front-line providers' well-being and heed their invaluable insights so that the Nation can recover faster and stronger. It is both a moral and strategic imperative for our Nation's leaders to do everything possible to arm and protect nurses and other critical responders as we work to combat the pandemic and prepare for future public health crises.

ANA SURVEYS ON PPE

Despite hopes that strong mitigation and containment actions in our communities would reduce the severity of the coronavirus outbreak, the Nation is currently seeing an uptick in COVID-19 cases, causing the demand for, and pressure on nurses to only grow. At the time of this testimony, PPE is not being provided in the quantity or quality that is required for nurses to safely care for patients. To closely and consistently monitor nurses' access to PPE, ANA has deployed several PPE-specific surveys, including two that were conducted in March and May, as well as one that is currently in the field. The findings of these surveys are outlined below, but the topline takeaway is that there has been little to no change in our members' access to sufficient quantities of safe and effective PPE since the beginning of the pandemic in the United States.

ANA's May survey on access to PPE received 14,000 responses. 45 percent of respondents reported PPE shortages in their facility, and 79 percent said they are required, or encouraged, to reuse single-use PPE, such as N95 masks. More than half of these respondents said they feel unsafe using decontaminated respirators. ANA does not support the use of decontamination methods as a standard practice; however, we have acknowledged this is a crisis capacity strategy. The Association recommends that Congress engage with the U.S. Food and Drug Administration regarding the need to expeditiously research the effectiveness of various decontamination methods for the reuse of PPE by nurses and other health-care professionals. We also urge additional oversight to ensure a return to best practices as soon as possible.

STORIES FROM THE FIELD

ANA has requested nurses from across the country share their personal stories related to PPE. It is evident from these stories that the PPE supply chain continues to be strained. While facilities struggle to supply adequate quantities of PPE, ANA is hearing that the quality of the PPE is getting worse. Nurses in Oregon reported that a large hospital system purchased and reported an ample supply of masks. Unfortunately, likely due to supply issues, the hospital switched brands, and the current stock of masks are all too large to properly fit most staff. This can cause safety issues because if the masks are too large, there is the potential to create an opening in which the virus may enter, putting healthcare workers at an even greater risk, as there is not a reliable seal around their face, which is mandated by the wearing of isolation gear.

Nurses also reported that the quality of the masks was so poor that the wire that forms around the nose did not fit properly, causing safety concerns over the tightness of the facial seal. These are not isolated examples. Congress and the administration, in coordination with the States, must ensure not only that health-care providers are stocked with adequate quantities of PPE, but also that it meets medical, safety, and quality criteria.

The top-line concerns that ANA has received in its surveys are as follows:

- Nurses are being asked to reuse PPE when reuse is out of alignment with manufacturers' guidelines.
- Facemasks fog up resulting in various incidents (needle stick, inability to accurately take blood pressure, etc.).
- Nurses being asked to reuse PPE that *cannot be disinfected*.
- That some personal protective equipment is unsafe. A soft, pliable face shield may be non-medical grade, warping and fogging material. The straps cannot be disinfected.
- In some locations there is an insufficient supply of PPE. Nurses are getting small allotments of gloves, disinfectant, surgical masks and N95s. These do not meet the need of the procedures the nurses are being ordered to perform.
- Underserved and rural hospitals are being outbid by larger health systems as well as both the State and Federal Government, exacerbating their difficulty in obtaining supplies.

ANA has also received over 200 personal stories as part of a PPE survey that is currently out in the field.

STRATEGIC NATIONAL STOCKPILE RECOMMENDATIONS

While ANA understands the PPE crisis is the result of multiple factors, including shortages of raw materials, a global need for equipment, and growing PPE needs as the country and schools reopen, we believe that more must be done by both the

Federal and State Governments to better deploy this protective equipment. While States certainly have a role in ensuring access to care, more needs to be done to enhance the Federal/State partnership to ensure transparency and equitable access to safe and quality protective equipment for health-care providers.

To achieve this goal, ANA recently submitted detailed recommendations to Chairman Lamar Alexander and the Health, Education, Labor, and Pensions (HELP) Committee in response to the chairman's white paper request, which is attached and summarized below.

- To make sure health-care providers are never again left with a PPE shortage, Congress should request an annual report on the state of the strategic national stockpile (SNS) with respect to PPE, vaccines, medicines, and other supplies. The report must include when items are expiring and what items need to be replaced. When items are approaching expiration, they should be donated to underserved medical facilities such as federally qualified health centers, rural hospitals, and clinics based on need.
- Health-care facilities should be required to report monthly on their levels of these items so the agency in charge has up to date information on where shortages may be most acute in the early stages of an emergency. A formulary should be developed by National Academy of Sciences, Engineering, and Medicine on what levels of PPE, vaccines, and other supplies health-care facilities should have in their own stockpiles. Manufacturers of these items should also be reporting on production and capabilities.
- The Federal Government must take appropriate steps to plan coordination efforts. Many States will not have the resources or expertise to carry out preparations or coordination without Federal assistance. Hospitals and facilities with more capital will most likely benefit while rural and underserved areas will suffer. There have been instances of States and health-care systems in competition with one another to procure PPE and essential supplies. The Federal Government needs to help States prepare by taking steps to ensure they are not pitted against each other when it comes to resources.
- The Federal Government needs to do more to incentivize and prioritize the manufacturing of PPE, medications, and other supplies in the United States, even if that means carrying out production itself. We cannot allow our citizens to be put at a health risk because businesses view manufacturing elsewhere better for their bottom line. More production in the United States will also help the U.S. economic recovery.

ANA ENGAGEMENT WITH THE FEDERAL GOVERNMENT REGARDING PPE

Since the beginning of this pandemic, ANA has called on Federal officials to increase the supply of PPE. The Association will continue to do so because nurses, other health-care professionals, and essential workers must have the proper equipment to protect themselves and take care of our communities. We have specifically urged the administration to use the Defense Production Act more aggressively to increase the domestic production of medical supplies and equipment desperately needed by front-line health-care personnel. With the rise in cases as States reopen, the administration and Congress must continue to increase and incentivize the domestic production of medical supplies and equipment that meets medical, safety, and quality criteria desperately needed by front line health-care personnel.

CONCLUSION

ANA stands ready to work with the Finance Committee, the entire Congress, and the administration to find sustainable solutions to this PPE crisis in order to protect our Nation's front-line nurses and ensure that front-line providers will never experience this level of shortage and unsafe practices again. On behalf of our patients and their families, the 4 million RNs who care for them, and the hundreds who have selflessly given their lives to safeguard the health of their communities, we must do better. Thank you and I look forward to answering any questions that you may have.

Attachments:

ANA response to the Senate HELP Committee white paper titled, "Preparing for the Next Pandemic," <https://www.nursingworld.org/practice-policy/work-environment/>

health-safety/disaster-preparedness/coronavirus/june-3-2020-prac-grant/june-26-ana-letter-to-chairman-alexander/.
 ANA May 2020 PPE Survey, <https://www.nursingworld.org/practice-policy/work-environment/health-safety/disaster-preparedness/coronavirus/what-you-need-to-know/survey-series-results/#:~:text=ANA%20Personal%20Protective%20Equipment%20Survey%20-%20May%202020,situation%20on%20the%20frontlines%20of%20the%20COVID-19%20pandemic>.
 ANA May 2020 PPE survey infographic, <https://www.nursingworld.org/~49cd40/globalassets/covid19/ppe-infographic-june-5-2020.pdf>.

ATTACHMENT 1

**ANA Responds to Questions From Chairman Alexander
 Re: Planning for the Next Pandemic**

ANA responded to questions from a white paper entitled, “Preparing for the Next Pandemic.” It looks to address future pandemics based on lessons learned from COVID–19 and the past 20 years of pandemic planning.

June 26, 2020

The Honorable Lamar Alexander
 Committee on Health, Education, Labor, and Pensions
 428 Dirksen Office Building
 Washington, DC 20510

Re: Pandemic Preparedness White Paper

Dear Chairman Alexander:

In the Pandemic Preparedness White Paper that was issued on June 9, 2020, the Committee requested input on what the United States has learned from the past twenty years of public health preparedness and response and how it can better prepare for future pandemics. On behalf of the American Nurses Association (ANA), I have provided recommendations for the Committee to consider as its work on COVID–19 and preparedness continues over the next several months.

Stockpiles, Distribution, and Surges—Rebuild and Maintain State and Federal Stockpiles and Improve Medical Supply Surge Capacity and Distribution

How can the Strategic National Stockpile be better managed and how can Congress increase oversight and accountability?

Congress should receive an annual report on the state of the Strategic National Stockpile (SNS) with respect to personal protective equipment (PPE), vaccines, medicines, and other supplies. The report must include when items are expiring and what items need to be replaced. When items are approaching expiration, they should be donated to underserved medical facilities such as federally qualified health centers, rural hospitals, and clinics based on need.

Health care facilities should be required to report monthly on their levels of these items so the agency in charge has up to date information on where shortages may be most acute in the early stages of an emergency. A formulary should be developed by National Academy of Sciences, Engineering, and Medicine on what levels of PPE, vaccines, and other supplies health-care facilities should have in their own stockpiles. Manufacturers of these items should also be reporting on production and capabilities.

In addition, the federal government needs to do more to incentivize and prioritize the manufacturing of PPE, medications, and other supplies in the United States, even if that means carrying out production itself. We cannot allow our citizens to be put at a health risk because businesses view manufacturing elsewhere better for their bottom line. More production in the United States will also help the U.S. economic recovery.

How can states and hospitals improve their ability to maintain a reserve of supplies in the future to ensure the Strategic National Stockpile is the backup and not the first source of supplies during emergencies?

They should be required to follow and report on the above-referenced formulary of how much of each item they must always have on hand. Without an incentive or penalty—financial or otherwise—there is little incentive to maintain larger reserves.

What steps should be taken to ensure that health-care providers and first responders have the supplies they need, such as personal protective equipment?

By following the recommendations above regarding better managing the SNS and improving how states and hospitals improve their ability to maintain reserves.

As states and hospitals establish or build their own stockpiles, how will they know what supplies to stockpile? What guidance should the federal government provide on what medical supplies are appropriate?

There should be a formulary developed by the Department of Health and Human Services, Centers for Disease Control and Prevention, National Academies of Sciences, Engineering, and Medicine, and other appropriate government agencies, departments, and other stakeholders, to determine what items are needed for their own stockpiles and what are appropriate levels of stock for each item.

Could states and hospital systems establish their own vendor managed inventory programs with manufacturers and distributors? Should the federal government or states contribute to such hospital stockpiles?

In theory they could, but quality conditions and maintenance will result in drastically varying consistency. Furthermore, neglect could occur in some areas due to budget cuts.

Public Health Capabilities—Improve State and Local Capacity to Respond

What specific changes to our public health infrastructure (hospitals, health departments, laboratories, etc.) are needed at the federal, state, and local levels?

A robust public health infrastructure better equips the nation with preparedness and response measures during times of crisis. This pandemic is the latest in a long string of emergencies that put a spotlight on what damage underinvesting in public health can do to a society. Federal reinvestment in public health infrastructure back to at least 2008 levels will be important as the nation moves forward.

Additionally, expansion of the public health workforce is a key element of this needed investment. Our public health workforce, of which public health nurses are the largest segment, touch every aspect of health care and community well-being. They play an integral role in narrowing disparities, improving health outcomes, and reducing disproportionately high morbidity and mortality rates due to preventable illness.

How can the federal government ensure all states are adequately prepared without infringing on states' rights and recognizing states have primary responsibility for response?

It is important for the federal government to take appropriate steps to plan coordination efforts. Many states will not have the resources or expertise to carryout preparations or coordination without federal assistance. Hospitals and facilities with more capital will most likely benefit while rural and underserved areas will suffer. We have seen instances of states competing with each other to procure PPE and essential supplies, and federal government coordination efforts, where appropriate, wouldn't seem to infringe on state responsibility. The federal government needs to help states prepare by taking steps to ensure they aren't pitted against each other when it comes to resources.

How should the federal government ensure agencies like CDC maintain an appropriate mission focus on infectious diseases in the periods between emergencies to strengthen readiness to respond when a new threat arises?

Congressional oversight as well as adequate funding are vital to ensure that the CDC and other relevant agencies stay focused and dedicate resources to improved readiness for future pandemics and public health emergencies.

ANA is the premier organization representing the interests of the nation's 4.1 million RNs, through its state and constituent member associations, organizational affiliates, and individual members. ANA members also include the four advanced practice registered nurse roles (APRNs); Nurse practitioners (NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs) and certified registered nurse anesthetists (CRNAs). ANA is dedicated to partnering with health-care consumers to improve practices, policies, delivery models, outcomes, and access across the health-care continuum.

Thank you for giving nurses this opportunity to provide the federal government with input on pandemic preparedness and public health. If you have questions, please contact Ingrida Lusic, Vice President of Policy and Government Affairs, at (301) 628-5081 or Ingrid.Lusic@ana.org.

Sincerely,

Debbie D. Hatmaker, Ph.D., R.N., FAAN
 Acting Chief Executive Officer/Chief Nursing Officer
 cc: Ernest Grant, Ph.D., R.N., FAAN, ANA President

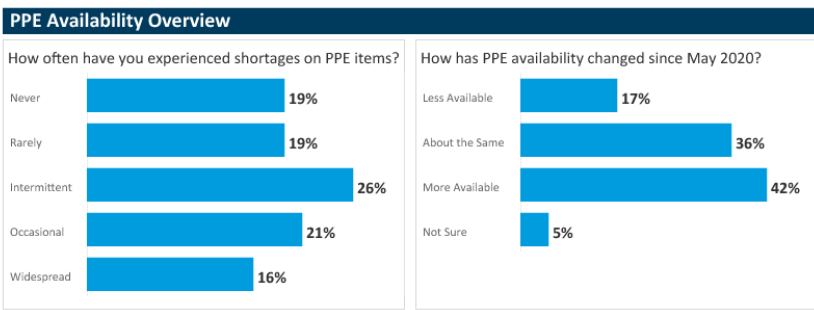
ATTACHMENT 2



COVID-19 Survey Series:
PPE Survey #2

US Respondents
 23,207

State of Employment: All | Employment: All | Role: All | Direct Care to COVID-19 Patients?: All



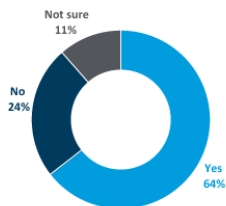
Specific PPE Item Breakdown

What is the status of specific PPE items at your facility?

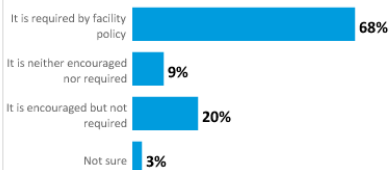
	I am out of this PPE	I am short of this PPE	I am moderately able to get this PPE	I am fully able to get this PPE	I typically do not use this PPE
Surgical Masks	2%	14%	24%	58%	2%
N-95 Respirators	9%	28%	27%	25%	12%
Gowns	3%	19%	25%	45%	8%
Face Shields	5%	18%	26%	42%	9%
Goggles	9%	16%	21%	35%	18%
Elastomeric Respirator	10%	8%	7%	7%	67%

Use of N-95 Respirators

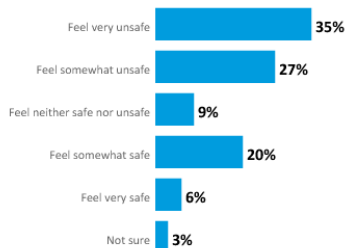
Did the N-95 masks you were given fit appropriately?



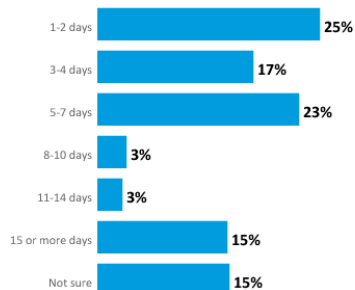
Are you required to re-use single use items such as N-95 respirators?



Do you feel safe with the approach in place to manage the re-use process?

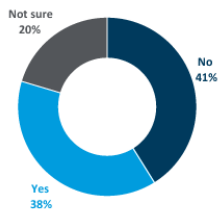


What is the # of days that you are required to re-use the same respirator?

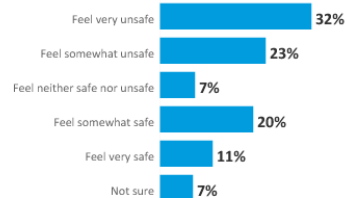


Decontamination of N-95 Respirators

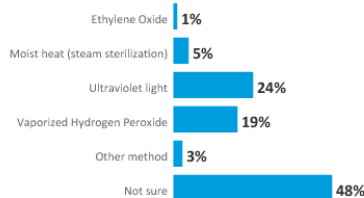
Is your facility decontaminating N-95 respirators?

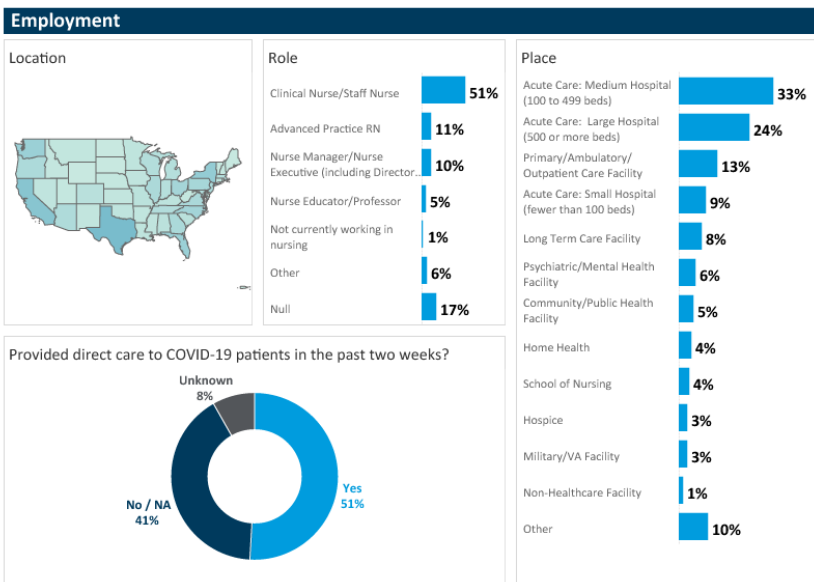


If your facility is decontaminating N-95 respirators, do you feel safe using a decontaminated respirator?



If your facility is decontaminating N-95 respirators, please pick which decontamination method is being used?





PULSE ON THE NATION'S NURSES

A COVID-19 Survey Series



All data was confidentially collected and de-identified, and is stored by the ANA Enterprise. This survey used convenience sampling; results cannot be generalized. Respondents may under- or over-represent the population. Results in any state with fewer than 50 responses should be regarded cautiously.

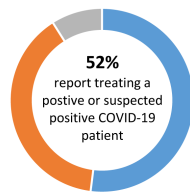
ATTACHMENT 3

**Personal Protective Equipment Survey
May 2020**

The American Nurses Association conducted a survey of nurses in May to understand their recent experiences and concerns related to the availability, reuse, decontamination and accessibility of Personal Protective Equipment in all healthcare settings during the COVID 19 pandemic.



Respondent Snapshot

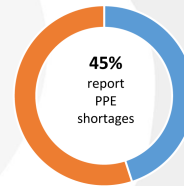
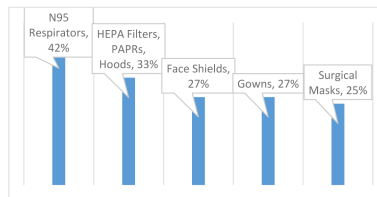


Representing All States and 3 US territories

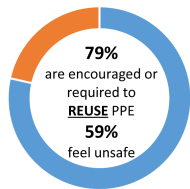


Personal Protective Equipment Shortages

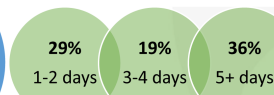
Large and Small hospitals and VA facilities experienced the least shortages
Long-term care and Community Health facilities experienced the most shortages



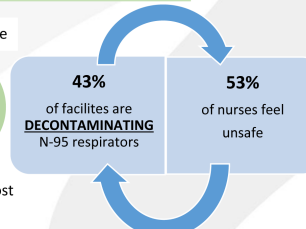
PPE Reuse and Decontamination



Number of days of N95 Respirator Reuse



LTC nurses reported reuse 5+ days the most



8515 Georgia Ave., Suite 400
Silver Spring, MD 20910
www.nursingworld.org

Data were collected through a survey administered by the American Nurses Association to identify needs and observations from nurses (members and non members) working during the COVID-19 pandemic. Between May 15-31, 2020, 14,328 nurses responded

QUESTIONS SUBMITTED FOR THE RECORD TO ERNEST GRANT, PH.D., R.N., FAAN

QUESTIONS SUBMITTED BY HON. RON WYDEN

Question. During the July 30th hearing, you testified that the difficulties rural and underserved medical settings have had obtaining personal protective equipment is leading to a “snowball effect” that exacerbates health disparities experienced by black, indigenous, Latinx and other communities of color. You noted during your testimony that you had additional thoughts and data that you could provide to expand on that point—please use this question to expand your views on the issue.

Answer. As the COVID–19 pandemic continues to evolve, it is clear that communities of color are disproportionately impacted. The Kaiser Family Foundation found that multiple analyses of available data demonstrate that people of color are not only more likely to contract the virus but have higher rates of mortality.¹ This is especially true in rural and underserved areas of our health care delivery system.

Health-care providers need PPE to successfully respond to and provide care for patients who have contracted COVID–19. Challenges faced by providers to obtain the necessary PPE hinders their ability to do so. We know that a medical center in rural Wisconsin had difficulty in gaining access to needed PPE. The same was true for underserved areas of Chicago—leading to widespread transmission of the virus.

In addition, patients in rural and underserved areas face barriers to access and needed health-care services—which the pandemic has only made worse. For example, many vulnerable populations rely on public transportation systems to be able to get to appointments. Local and State COVID–19 mitigation plans resulted in the discontinuation or restriction of public transportation services, which continues to directly impact the ability of patients to access needed care. The pandemic also highlighted the need for a highly educated and trained health-care workforce representative of all residents in every community is essential to not only treat but prevent outbreaks through trusted education.

These factors only serve to exacerbate existing health disparities among people of color and must be addressed. It is critical that Congress addresses the challenges faced by providers in acquiring needed, quality PPE as they continue to respond to the COVID–19 pandemic.

Question. Observers have noted that rural hospitals and healthcare providers faced difficulties obtaining PPE in the early days of the pandemic in part because it wasn't where the pandemic was centered. Now the pandemic has progressed there and we have heard anecdotally that those supply problems persist as smaller operators compete against larger buyers, States and the Federal Government. In many cases, these rural providers are providing care to black, indigenous and Latinx and other communities of color, which as you noted, and the PPE shortages exacerbate racial health disparities. Assuming that a viable vaccine is approved, what lessons can be drawn from the experiences with PPE and testing to ensure health disparities in these communities aren't further worsened? What steps can the Centers for Medicare and Medicaid Services take to ensure broad distribution to rural and underserved communities?

Answer. It cannot be over-stated that all individuals must have access to the vaccine—especially in rural and underserved areas. It is critical that education about the need for all individuals to receive the COVID–19 vaccine begins now. That also means that clinical trials and post-marketing studies must include pregnant women and individuals of all ages, races, nationalities and health conditions. Public service announcements on television and radio can convey factual, science-based reasoning on the importance of the vaccine. Partnering with community leaders will allow for further dissemination of information, such as in places of worship, social service organizations, and local community centers. Elected officials can help by getting vaccinated themselves and promoting it to their constituents. As the vaccine becomes available and is distributed, these channels can be used to provide additional information on how and where to access the vaccine.

Nurses are a critical component in vaccine education and distribution. Nurses remain on the front lines of the pandemic, and their relationships with patients can be leveraged to ensure vaccine adherence. Nurses can be hired to monitor and ensure patients receive the full course of the vaccine. They can aid in breaking down transportation barriers by bringing the vaccine to where patients are in the community. Other barriers can be simply addressed by allowing nurses to offer extended hours for vaccine administration and using school-based settings to ensure entire families are vaccinated. Furloughed nurses also can be hired to administer vaccines, as well as nursing students needing to meet clinical hour requirements. These are just some examples of how nurses can ensure rural and underserved populations have access to the COVID–19 vaccine.

The Centers for Medicare and Medicaid Services (CMS) must work with other Federal agencies and community partners to ensure education about the vaccine is

¹ <https://www.kff.org/coronavirus-covid-19/issue-brief/covid-19-racial-disparities-testing-infection-hospitalization-death-analysis-epic-patient-data/>.

disseminated and that the vaccine is broadly distributed to ensure patient access—especially, for rural and underserved areas of the health-care delivery system. Existing community support should be leveraged to provide the vaccine to communities already faced with barriers to health-care services. CMS and Medicare Advantage plans must make clear to Medicare beneficiaries how to access the vaccine and work with State agencies to ensure the vaccine is available to Medicaid beneficiaries and children enrolled in the Children’s Health Insurance Program (CHIP).

In addition to administrative action, Congress must provide the resources needed to ensure broad distribution of the vaccine, specifically targeting rural and underserved communities. Congress can also address how uninsured populations can access and receive coverage for the vaccine, similar to how it addressed testing and treatment of COVID–19 for uninsured patients. As noted above, the populations in these communities are disproportionately impacted by the pandemic, which highlights the challenges stemming from racial health disparities. Resources to support targeted, intentional distribution of the vaccine is critical to ensure racial health disparities are not further exacerbated.

Question. The Trump administration has relied on the practice of reusing PPE to make it look like there are adequate supplies at hospitals and other medical settings, which has been a big safety concern for workers. Your organization surveyed 14,000 nurses in May and found that 45 percent worked at facilities with shortages of PPE, and 79 percent reported having to reuse PPE. In July, the National Nurses Union released a survey of 21,000 nurses, of which 87 percent reported re-using PPE. My staff heard similar stories from around the country. One nurse in Houston, where the virus is surging, told Minority staff that her hospital is cleaning and reusing N95 masks up to 10 times. Dr. Grant, what concerns do you have regarding the reuse of PPE that intended for a single use?

Answer. Nurses on the front lines of the COVID–19 response, faced by continued shortages, continue to have serious concerns about reusing PPE. In our July 2020 PPE survey of 21,000 nurses, 68 percent of nurses reported they are required to reuse N95 respirators. Of those who reuse N95 respirators, 58 percent report reuse for 5 or greater days. 62 percent of nurses feel unsafe with current reuse practices.

The ANA does not support the use of decontamination methods as a standard practice. However, as we are faced with a crisis, we acknowledge alternative capacity strategies must be utilized, but this does not eliminate the need for establishing the appropriate safeguards and quality control measures.

ANA strongly recommends that Congress engage with the U.S. Food and Drug Administration to expeditiously research the effectiveness of various decontamination methods for the reuse of PPE by nurses and other health-care professionals. We ask that you take into consideration the current practice of extended use within a single shift and reuse over multiple days as decontamination practices are evaluated. A 2012 study cites degradation in form and fit of N95 respirators following 5 don and doff cycles independent of the current extended use practices over an 8–12 hour or longer shift. Further, we encourage Congress to examine the need for additional oversight on supply, distribution, and facility policy and how best to expeditiously return to best practices.

Question. What steps should the Federal Government take to secure adequate PPE supplies?

Answer. There are many steps the Federal Government can take to ensure adequate supply of PPE for health-care providers across the country. First, the Defense Production Act (DPA) must continue to be enforced as well as, better management of the strategic national stockpile (SNS). Congress should receive an annual report on the state of the SNS with respect to personal protective equipment (PPE), vaccines, medicines, and other supplies. The report must include when items are expiring and what items need to be replaced. When items are approaching expiration, they should be distributed based on need to underserved medical facilities such as federally qualified health centers, rural hospitals, and clinics.

Health-care facilities should be required to report monthly on the inventory of these items to allow for up-to-date information to determine where shortages may be most acute at any stage of a public health emergency. Such reporting should include number of staff and sizing needs to address appropriate fit of PPE. A formulary should be developed by the National Academy of Sciences, Engineering, and Medicine on what levels of PPE, vaccines, and other supplies health-care facilities must have in their own stockpiles. Manufacturers of these items should also be reporting on production levels and capabilities.

Currently, the Nation continues to face a pandemic, at the same time as hurricane season, fire season in the West, and the beginning of influenza infections. Hurricane season puts more strain on health-care facilities and providers due to frequent trauma related incidents and physical damage to facility and employee property. Widespread community transmission of the flu has the potential to further strain the health-care delivery system, with infected patients overwhelming facilities already at capacity. As the Nation looks forward and addresses readiness and response to the rising incidence of pandemics, Congress must take steps to ensure that the SNS is the backup and not the first source of supplies during any public health or other emergency.

Question. The Trump administration testified in July that it has used the Defense Production Act “more than 10 times” to combat COVID-19, an extraordinarily narrow use of existing authority that stands in stark contrast to Federal agencies historical use of DPA. Historically, the statute’s authority has been used to acquire supplies and services in times of emergency and in day-to-day business. For example, the Department of Defense places approximately 300,000 rated orders annually, while the Department of Homeland Security, including FEMA, placed more than 1,000 rated orders and contracts in 2018. Specific examples include using priority orders to acquire the Adenovirus vaccine, expediting construction of floodwater controls in New Orleans, speeding up the purchase of railroad equipment following Hurricane Katrina, and obtaining resources needed to house and feed disaster survivors and first responders, communications equipment and information technology needs, and other logistical needs supporting disaster response and recovery efforts. Given the shortages of PPE you have experienced, shouldn’t the administration use the Defense Production Act to increase the availability of personal protective equipment and better allocate supplies?

Answer. We do not know when this crisis will end or how many additional waves we will go through. The administration should use the Defense Production Act (DPA) to increase the availability of PPE. In March, the ANA, American Medical Association, and the American Hospital Association sent a letter to President Trump urging the administration to fully invoke the DPA and ensure that N95 respirators, isolation gowns, isolation masks, surgical masks, eye protection, intensive care unit equipment, and diagnostic testing supplies are fully stocked across the country.

QUESTION SUBMITTED BY HON. MARIA CANTWELL

Question. In my State, health-care workers are reporting a noticeable decline in the quality of PPE available to them.

I spoke with a cancer care nurse from Swedish Hospital in Seattle who said that she and her colleagues are forced to reuse the PAPR hoods in the hospital to the point that they are being held together by duct tape.

What are your members across the country reporting to you in terms of the quality and availability of PPE that they are receiving?

Answer. ANA has requested nurses from across the country to share their personal stories related to PPE. It is evident from these stories that the PPE supply chain continues to be strained. While facilities struggle to supply adequate quantities of PPE, ANA is hearing that the quality of PPE is getting worse.

Nurses in Oregon reported that a large hospital system purchased and reported an ample supply of masks. Unfortunately, the hospital switched brands and the current stock of masks are all too large to properly fit most staff. Nurses also reported that the quality of the masks was so poor that the wire that forms around the nose did not fit properly, causing safety concerns over the tightness of the facial seal. Further, some PPE produced overseas may not meet NIOSH standards, raising serious concern about the efficacy of the PPE.

In addition to the safety concerns, ill-fitting or low-quality PPE wastes the limited resources of health-care facilities. The continued decline of supply and/or quality PPE is especially critical as we begin influenza season amid the ongoing COVID-19 pandemic. Nurses must be able to rely on PPE that will protect them and other patients as they remain on the frontlines of the ongoing public health emergency.

QUESTIONS SUBMITTED BY HON. DEBBIE STABENOW

Question. My colleagues raised questions about the impact of the pandemic on the mental health of nurses and front-line workers, which we must address with urgency. We also know that the pandemic has negatively affected the mental health of Americans not serving on the front lines.

You spoke in your testimony to the mental health effects on nurses. What resources do you anticipate frontline workers like nurses needing to respond to increasing mental health emergencies that may result from the pandemic's effects? Have nurses observed an increase in patients with mental health challenges that they encounter in their work while they respond to this pandemic?

Answer. It is imperative that nurses are aware of and have access to mental health services as they continue to respond to the COVID-19 pandemic. The pandemic has escalated burnout, anxiety, depression, and fear of stigma among front-line health-care professionals. In a report by the International Council of Nurses (ICN), 60 percent (20 out of 33) of responders sometimes or regularly received reports of mental health distress among nurses during the COVID-19 public health emergency.

In recognition of the need to support nurses during this unprecedented time, the American Nurses Foundation launched The Well-Being Initiative. In partnership with the American Nurses Association, American Association of Critical Care Nurses, American Psychiatric Nurses Association and the Emergency Nurses Association, this initiative offers responsive and preventative resources to support all nurses' mental health and resilience as they continue to serve on the front lines of this public health emergency. The Initiative includes virtual support systems, a curated digital toolkit, and expressions of gratitude.

In addition, it is critical that nurses who are serving on the front lines are adequately compensated and given time off. While this does not directly address the mental health effects of the pandemic, these factors are important to ensure nurses are recognized and supported. The need for nurses to receive hazard pay cannot be overstated. Nurses on the front lines not only put their lives at risk, but are critical in successful response to and mitigation of COVID-19 outbreaks.

Further, the pandemic continues to disrupt the lives of all Americans. The economic downturn due to the pandemic has led to great uncertainty—fear of losing one's house or job is a source of great stress and anxiety. Others have been directly touched by the pandemic, losing loved ones to the virus without the ability to be by their bedside or attend funeral services because of COVID-19 mitigation efforts. For those with existing mental health or substance use disorder needs, including veterans struggling with post-traumatic stress disorder, response to the pandemic has exacerbated their challenges. Patients that relied on in person support meetings now must rely on virtual support, which poses new challenges as not all patients have access to stable, adequate Internet. This has resulted in an increase in patient mental health needs. Nurses are increasingly seeing patients faced with a mental health or substance use challenges, which can potentially complicate patient recovery from COVID-19. Just as it is critical that nurses have knowledge of and access to mental health services, patients must as well.

Question. Senator Casey mentioned the need to innovate on PPE for health-care workers as we respond to this pandemic and prepare for the future, an effort I am proud to work with him on. What are the most pressing PPE issues facing front-line workers to address in future innovation?

Answer. Congress needs to do more to incentivize and prioritize the manufacturing of PPE, medications, and other supplies in the United States—even if that means carrying out production itself. We cannot allow our citizens to be put at a health risk because businesses are profit-motivated to manufacture elsewhere. As this pandemic has clearly illustrated, it is imperative the United States have stable supply chains so that the health-care delivery system can respond to any public health emergency. In addition, increasing domestic production can also help the Nation recover from the economic downturn resulting from the COVID-19 pandemic. Domestic production is critical so that our Nation's health-care providers have access to adequate amounts of quality PPE to ensure they are safe serving on the front lines.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

Question. What do you believe is the most important action that this Congress or administration can take to ensure the safety and vitality of our Nation’s health-care workforce through the remainder of the COVID–19 pandemic and in anticipation of future public health threats?

Answer. The COVID–19 pandemic has highlighted the need for Congress and the administration to examine and address workforce shortages. With an aging population, a robust health-care workforce is crucial to ensure patient access to needed services. In addition, we need to reinvest in our public health workforce and infrastructure. Multiple years of funding cuts contributed to more than 55,000 lost jobs at local health departments from 2008–2017.² This could help identify illness earlier within communities and stop the spread of COVID–19, reduce other health-related issues, and put our health-care system on a stronger foundation.

In response to the COVID–19 pandemic, the administration was quick to remove barriers to workforce and licensure requirements that allowed for full deployment of health-care providers to respond to the public health emergency. Congress and/or the administration should examine which barriers should be permanently removed to bolster the vitality of the Nation’s health-care workforce now and for the future. This includes, but not limited to, full practice authority for nurses, payment parity for telehealth services, and scholarships and loan forgiveness programs for clinicians working in areas with workforce or appointment shortages.

Last, as detailed above, health-care providers must have access to adequate supply of quality PPE for their safety. This has been especially true for the COVID–19 pandemic. Congress and the administration must take steps to ensure that providers have the supplies they need to prepare for and respond to any future public health threat.

Question. What more should Congress be doing to prepare for the upcoming flu season and its impact on the ongoing COVID–19 pandemic?

Answer. Congress can ensure that Federal agencies, States, and the health-care delivery system have the resources and support needed to prepare for the upcoming influenza season. Congress and Federal agencies can take similar steps that we detail above for the COVID–19 vaccine to educate about the importance of and ensure access to the influenza vaccine. Efforts to educate in tandem can reinforce the importance of both vaccines—which is critical in ensuring the health care delivery system is not potentially overwhelmed by concurrent public health emergencies.

PREPARED STATEMENT OF HON. CHUCK GRASSLEY,
A U.S. SENATOR FROM IOWA

Good morning. I’d like to welcome everyone to Part 2 of the committee’s hearing on “Protecting the Reliability of the U.S. Medical Supply Chain During the COVID–19 Pandemic.” This is the second hearing to discuss COVID–19’s effect on our Nation’s medical supply chain.

Two days ago, we heard from the Department of Homeland Security’s Office of Procurement, U.S. Customs and Border Protection, and U.S. Immigration and Customs Enforcement’s Homeland Security Investigations, on their efforts to shore up the integrity of our Nation’s supply chain.

Today, we will hear from a panel of industry experts who represent all corners of the supply chain. These witnesses have an insider’s perspective and will be able to tell us about the challenges our Nation’s health-care industry is facing right now. We will also hear how the Federal Government is collaborating and communicating with its industry partners during the pandemic.

Indeed, during our first hearing we heard that DHS is engaged in a whole-of-government response to combat the virus and is working with its Federal, State, local, tribal, and international partners in a unified effort to ensure the integrity of our Nation’s supply chain. For example, we heard from Homeland Security Investigations on their efforts to prevent and investigate criminal activity surrounding the pandemic, and how they seized hundreds of items of fake and faulty personal protective equipment and returned over \$17 million dollars to victims of COVID–

² <https://www.tfah.org/article/new-tfah-report-persistent-underfunding-of-americas-public-health-system-makes-the-nation-vulnerable-and-puts-lives-at-risk/>.

19 fraud. We also heard from DHS's Chief Procurement Office on their efforts to cut bureaucratic red tape so that FEMA could easily procure larger volumes of emergency services and supplies.

These are things that front-line workers desperately need, and DHS answered the call by working with industry to review and vet companies offering COVID-19 solutions to the Federal Government. I want to highlight that this continues to be an incredible challenge, as thousands of unscrupulous sellers claim to be able to produce safe and legitimate supplies when what they are actually selling is fake and faulty.

Lastly, we heard from Customs and Border Protection on their efforts to speed up the delivery of high-demand personal protective equipment from manufacturers overseas. As a result of CBP's efforts, over 1.3 billion pieces of personal protective equipment entered swiftly into the United States.

The list goes on and on, with many of these efforts being initiated at the beginning of the virus's foothold in the United States. However, my colleagues on the left aren't telling the public these success stories. They would rather spread their doom-and-gloom narrative for the purposes of winning the election.

It's a fact that the Federal Government's approach to emergency preparedness has always been fraught with challenges. This goes back to prior administrations and beyond. However, my Democratic colleagues would make you believe that these problems are specific to this administration. This is simply not true, and we have several witnesses before us today who can testify to this very fact, which I will state simply here and now: the Federal Government has never been prepared to address a national emergency of this type, or of this scale—period.

In closing, I want to thank the witnesses present today, and all the medical professionals and first responders who work day after day to keep Americans safe and healthy. Your dedication to your community is essential in the days and weeks ahead.

PREPARED STATEMENT OF CHARLES JOHNSON, PRESIDENT,
INTERNATIONAL SAFETY EQUIPMENT ASSOCIATION

Chairman Grassley, Ranking Member Wyden, and members of the committee, thank you for the opportunity to appear before you today to discuss the major challenges and potential solutions in protecting the reliability of the U.S. medical supply chain during the COVID-19 pandemic and beyond.

The International Safety Equipment Association (ISEA) is the association for safety equipment and technologies—equipment and systems that enable people to work in hazardous environments. ISEA member companies are leaders in safety equipment design, manufacturing, testing, and application. For more than 85 years, ISEA has set the standard for personal protective equipment (PPE) and technologies, supporting the interests of its member companies who are united in the goal of protecting the health and safety of people worldwide.

ISEA is a recognized leader in the development of ANSI-accredited safety equipment standards, in the U.S. and around the world. The association and its members work with Congress and government agencies to consult with policymakers whose decisions affect the industry. Over the course of ISEA's 85-year history, the industry has stepped forward to aid the United States in the face of various emergencies, from natural disasters to terrorist attacks, and certainly for public health emergencies. When these events occur, ISEA members provide the equipment that protects responders, medical professionals, and the public.

ISEA's member companies have been challenged on two fronts throughout the COVID-19 pandemic:

1. First, the safety and efficacy of the PPE used to combat the COVID-19 pandemic has been compromised by opportunistic market behavior. The incredible increase our member companies have seen in counterfeit, fraudulent, and non-performing equipment is of great concern to the manufacturers of, and more importantly, the users of, PPE.
2. Second, the overall capability of the US to provide protection during this pandemic has been sorely tested. We must improve our overall preparedness to handle the remainder of the COVID-19 pandemic, but more importantly,

there are improvements to preparedness that must be undertaken so that we can better respond to the next inevitable emergency.

MAINTAINING THE SAFETY AND EFFICACY OF PPE SUPPLIED
FOR PUBLIC EMERGENCY RESPONSE

Standards and Conformity

The safety equipment industry is built on a foundation of standardization, certification, regulatory compliance, and conformity. Most PPE products are as much items of intellectual property as they are physical barriers to injury or sickness. The standardized performance, the conformity of the product to that standard, and the accurate communication of that standard and conformity, are central to the value that PPE provides to the wearer. In many cases, the user hopes to never see a true test of a PPE product's performance in the field, yet they rely on that performance to keep them safe. They must trust the safety performance that has been communicated to them for a particular type of protection will occur.

Nowhere is this more evident than during the response to a national emergency, and most especially for new and novel threats such as a novel virus. When the medical community faces an unknown new pathogen, the state of the science must evolve quickly, and recommendations for protective equipment may do so as well. In these cases, the performance of the safety equipment must be a known, quantified parameter. If the CDC says a respirator that filters 95 percent of contaminants is adequate protection, then the respirators sourced by responders must reliably provide that level of standardized protection.

Opportunistic market behavior in the PPE sector leverages value of the standardization and conformity of branded, standardized, or certified safety equipment, and falls into three large categories:

1. Counterfeit products are marked or labeled with a known brand name and trade on the trust that the brand owner has built in the market—that their product is standardized and that it conforms to that standard, and that the user can trust that it provides the level of protection to which it attests.
2. Fraudulent products make false claims about their certifications, or the bodies that have provided testing.
3. Non-performing products either intentionally or unintentionally, do not meet the standards or certifications to which they attest.

ANSI/ISEA 125–2014: NATIONAL CONSENSUS STANDARD TO ASSURE PRODUCT LEGITIMACY

ISEA has published a national consensus standard designed to help end-users and PPE purchasers confirm the products they are purchasing are legitimate. ANSI/ISEA 125–2014—American National Standard for Conformity Assessment of Safety and Personal Protective Equipment is an approved method to encourage manufacturers or importers to attest to the veracity of their products. The ANSI/ISEA 125–2014 standard creates three levels of conformity assessment, by which the manufacturer or importer communicates to others the certainty of conformance to the PPE manufacturing standard. Level 1 is a self-declaration of conformity. Level 2 requires identification of accredited test labs that have tested the product to its relevant standard(s). Level 3 is a full third-party certification. This is used when product failure will result in death or severe harm to the wearer.

When ANSI/ISEA 125 is incorporated into another manufacturing standard, an end-user, procurement officer, or government official can ask the manufacturer for the product's conformity assessment declaration. While it is possible for an unscrupulous entity to provide a fraudulent test report, this standard is to help promote product legitimacy.

Voluntary product standards are a hallmark of the United States system of PPE standardization, and have been incorporated into the U.S. system for PPE use in occupational safety. Some PPE, for instance, respirators, are separately certified by government entities. In recent years, increased imports and entry of more and newer actors in the marketplace have led to both intentional, and possibly unintentional, abuse of these systems.

ISEA has previously brought these issues to the attention of various US agencies, including Department of Commerce, Customs and Border Control, and OSHA, and we will continue to explore solutions. As discussed below, the industry has seen an increase in false claims tied to standards during the COVID–19 pandemic. ISEA and its members continue to explore policy solutions for the issue of nonperforming

PPE, and we recommend that this issue be addressed by future counterfeiting initiatives recommended below

Counterfeits, Fakes, and Frauds

ISEA welcomes the committee's focus on Protecting the Reliability of the U.S. Medical Supply Chain During the COVID-19 pandemic. ISEA is proud to be a member of the National Association of Manufacturers (NAM) and we would like to associate ourselves its recent call to action, "Countering Counterfeits: The Real Threat of Fake Products," to battle against counterfeit goods, across the board.¹

ROLE OF DHS IN PREVENTING HARMFUL IMPORTS

First, ISEA applauds Customs and Border Patrol (CBP) and Homeland Security Investigations (HSI) for the agencies' dedication to stopping fraudulently marked and counterfeit COVID-19-related products from entering the U.S. Fakes, frauds, and counterfeits have always plagued the PPE sector, and these illegal products don't just harm the financial interest and the brand trust of our members, they put users at risk of injury, sickness, and death.

The Association understands that while most seizures during the COVID-19 pandemic are of illicit respirators and surgical masks, additional types of PPE interdicted by Federal authorities include clear face shields, safety goggles, protective suits, gloves, medical gowns, and protective shoe coverings. A wide range of other fraudulent COVID-19-related items have also been identified and seized. This process works, but it can work better, as we note below with a few suggestions.

ISEA MEMBER EFFORTS TO PREVENT ILLEGITIMATE IMPORTS

Supplementing the work of DHS, ISEA members view the import of fraudulently marked and counterfeited PPE seriously. For example, 3M Company has: (1) taken down 10,000 false and deceptive social media posts; (2) removed 7,000 fraudulent e-commerce offerings; (3) removed more than 140 deceptive Internet addresses; and (4) more.² The company is also investing in ways to identify fraudulently marked and counterfeited products. It is not just large companies that are the victims of this nefarious activity—but the largest companies are able to devote significant resources to protecting their brands, and the safety of their products.

Small and medium-sized manufacturers are likely to be harmed the most by the counterfeit market. These companies have fewer resources to invest in the personnel and technology to monitor illicit activity and protect their brands. Government enforcement efforts often rely on information provided by brand owners, and smaller manufacturers are less able to engage with government entities responsible for enforcing their IP right and fighting against fraudulently marked products. Smaller firms are also more at risk to be driven out of business by counterfeiters. They often offer fewer products than larger counterparts, which means harm from counterfeits cannot be easily offset. Smaller firms are less able to absorb the losses that come when counterfeiters siphon off their business.

NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH, PPE MANUFACTURERS
INFORM END-USERS OF FAKE OR FRAUDULENT RESPIRATORS

In addition to CBP and HSI, the National Institute for Occupational Safety and Health (NIOSH) National Personal Protective Technologies Lab (NPPTL), based in the Pittsburgh area, has identified a large number of respirators fraudulently marked with the NIOSH moniker and falsely claiming to be a NIOSH-certified product.³ The vast majority of these are from China. However, there are also several manufacturers based in China with NIOSH-approved N95 respirators.

NIOSH/NPPTL also performed filtration efficiency tests of several non-NIOSH certified respirators from China. Most exporters claim conformance to China's GB2626 standard. The results of the filtration efficiency tests show these devices removed 95–100 percent of the test particles. However, a few models had filtration performances below 50 percent, and some as low as 30 percent. Those with such low performance rates could be fraudulently marked as meeting the GB2626 standard. It was NIOSH's testing of respirators that led the Food and Drug Administration

¹ <https://www.nam.org/wp-content/uploads/2020/07/CounteringCounterfeits.vF.pdf>.

² https://www.3m.com/3M/en_US/worker-health-safety-us/covid19/covid-fraud/?utm_medium=redirect&utm_source=vanity-url&utm_campaign=3m.com/covidfraud.

³ <https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html>.

to cull its list of non-NIOSH respirators from China allowed for use in medical workplaces for protection from COVID-19.

Finally, we note that ISEA member companies have stepped in to combat the issue of nonperforming, or fake, PPE. Free testing provided by ISEA member companies is available to PPE users when they suspect the PPE they have sourced is nonperforming or substandard. In one case, an ISEA member found non-NIOSH certified respirator (KN95) masks to range from 45 percent–30 percent in efficiency. This catastrophically inadequate product was marked as FDA approved, making it fake and illegal. When ISEA member Magid Glove and Safety tested 10 foreign respirators, eight failed and two passed. The PPE manufacturer and distributor based out of Romeoville, IL, cited one example in which the fake respirator was no different than wearing a bandana on the face.

NEED FOR STRONG GOVERNMENT-WIDE COORDINATION ON IMPORT PROTECTION EFFORTS

With NIOSH's contribution to this area in mind, ISEA would like to underscore NAM's call for a range of import security reforms.⁴ One that is applicable here is **for creation and funding of a White House agency that holds primary responsibility for U.S. anti-counterfeiting efforts, including strategy, policy and enforcement. The new White House agency should serve as a central point of contact for the private sector and other stakeholders.** This type of coordination center might allow for NIOSH to train and inform the Nation's import security professionals. NIOSH does not have enforcement authority. When it finds a company illegally using the NIOSH logo, the agency's only mechanism is to send a letter requesting the counterfeiter cease and desist.

ONLINE RETAILER RESPONSIBILITY NEEDED

ISEA's largest companies have found Amazon and other online retailers to be responsive in removing counterfeit products. ISEA applauds the ecommerce platforms that worked cooperatively with PPE manufacturers and the government to crack down on the sale of these illicit products. The Association believes all parties can build on this success and momentum.

ISEA asks Congress for legislation mandating that online sellers audit their sites for fake, fraudulent and counterfeit PPE and other products, and remove them. ISEA joins with NAM in calling for legislation to hold online retailers partially responsible (contributory liability) for any injuries arising from the use of fake, fraudulently marked or counterfeited products sold on their platforms.

COVID-19 has led to increased cybercrime and misinformation, preying upon consumers looking to keep themselves and their families safe. These criminals require domain names, which can also include phishing and malware campaigns, selling dangerous counterfeits and setting up scam sites.⁵ The value of WHOIS data (domain name registrations) is widely known throughout the cybersecurity community. But law enforcement and IP holders have effectively been blocked from accessing this critical data. But access to this data serves the public interest and contributes to the security of the Internet by providing contact information to support efforts related to consumer protection, cybercrime investigation, domain name system (DNS) abuse mitigation, intellectual property protection, and for appropriate law enforcement needs. **ISEA believes legislation is also needed to allow Federal law enforcement authorities and IP holders to identify the individuals behind the websites and electronic front companies offering non-legitimate products.**

CHINA'S EFFORTS TO PREVENT FRAUDULENT EXPORTS

China's Ministry of Commerce (MofCom) has helped to some degree in preventing fraudulently marked protective equipment from leaving the country. In one case, MofCom officials prevented the export of protective garments because they did not claim to meet a specific standard. In China, these products must meet the local performance standard. But products were destined for the U.S. market, where there is no government standard. ISEA intervened by explaining that in the U.S. there is no government standard for these products, and their arrival at Customs would not cause an issue.

⁴ https://www.nam.org/wp-content/uploads/2020/07/CounteringCounterfeits.vF_.pdf.

⁵ <https://www.sec.gov/news/press-release/2020-97>.

Ensuring the Adequate Supply of PPE During Surge Demand Due to Public Emergencies

ISEA was an original partner with the Federal Government when the strategic national stockpile (SNS) was implemented. Our member companies have participated in successive rounds of preparedness planning, all of which identified the need for a public policy solution for the issue of surge demand during large scale public emergencies.

Like all other manufacturers, the safety equipment industry has adopted just-in-time supply chain and inventory management. Manufacturers do not have the option to maintain excess production capacity or product inventories. Competitiveness is directly linked to logistics efficiencies. Manufacturers are not emergency planners or emergency response agencies.

These market forces also affect the ability of end user entities such as large hospital locations from carrying extensive inventories of the various equipment that would be needed for all public emergency scenarios.

Public policy solutions will be needed to address future surge capacity comparable to what we have seen in the first half of 2020, and ISEA will partner with the agencies tasked with that challenge.

ISEA asks Congress to provide FEMA with authority during a public health emergency to gather data from State and local governments and health-care providers regarding the supply, use, and demand for PPE (as well as similar supply data from raw material suppliers, manufacturers and distributors). This will ensure optimal distribution decisions can be made based on real-time data.

Direct and Sustained Support for Domestic Production

The use of the Defense Production Act (DPA) is new for the PPE industry, as for others. ISEA members have found the use of the DPA to have positive and negative consequences.

The Federal Emergency Management Agency's (FEMA) quick action to prevent exports of filtering facemasks respirators, reusable respirators, and the replacement filters for them will have a long-term negative impact on U.S. manufacturers of these devices. Foreign customers will find other sources to supply respirators and the requisite replacement filters. Once the new products are part of an end-user's health and safety operation, on which employees are trained, end-users are not likely to switch back.

In relation to PPE supply for the pandemic, any short-term increase in supply in the U.S. domestic market would be more than offset by retaliatory bans from trade partners, not just on PPE products, but potentially on the supply of materials and components for U.S. manufacturers.

On the other hand, DoD's use of title III of the DPA resembled the type of public-private partnership that aids both U.S. manufacturers' and the Federal Government's ability to provide necessary equipment and products. As the medical industry stepped up its sourcing of PPE at the beginning of the outbreak to unprecedented levels, established market signals that regularly allocate product broke down.

ISEA is aware that large orders for PPE were fulfilled in regions that were not yet heavily impacted by the outbreak while early heavily affected areas scrambled for equipment. At the same time, responding agencies approached the industry with supply data inquiries, but without data or forecasting for the demand side of the equation. Use of the DPA model allowed the Federal Government to provide a clear and concise demand signal to the industry for efficient and accelerated response.

Recent and well-publicized actions include capital funding for both 3M's personal safety division and Honeywell Safety Products to expand production of filtering facepiece respirators. Other respiratory protection manufacturers have also received DPA funding through the Defense Department for expansion of filtering facepiece respirator production.

ISEA would like to highlight these successful examples of government and industry working cooperatively to solve a national issue.

As Congress and the executive branch continue to focus on public health emergency response, **ISEA asks that legislators focus on direct and sustained support of domestic PPE production.** All too often this industry has been flooded

with orders only to see them disappear after the public health emergency is fully mitigated.

ISEA asks Congress to recognize medium sized employers do not have the ability to reshore operations and supply chains. In addition, medium-sized companies seek steady growth. For these companies, the effort required to respond to a one-time request for proposal from the government takes away from managing day-to-day issues, which include executing on strategic growth plans. **ISEA asks that Congress not cut these companies out of SNS supply opportunities because they have not fully reshored all operations.**

SNS Funding and Mandate

ISEA supports Senator Alexander’s recently introduced Preparing for the Next Pandemic Act, which supports long-term funding for both State and Federal stockpiles. This type of long-term commitment is needed to encourage more U.S. companies to enter the U.S. supply market.

In past public health emergencies, PPE manufacturers found that end-users submitted duplicate orders to multiple providers, which inflated demand. As soon as the emergency abated, the orders were canceled. This left many distributors and manufacturers wary about fully responding to future pandemics. In fact, for COVID–19, many manufacturers told customers that orders were un-cancelable. In addition, many medium-sized manufacturers cannot risk reshoring their operations, which would both be a costly enterprise and increase the costs of manufacturing, only to find that U.S. public health stockpiling funding has fallen short for various reasons. A long-term commitment to maintaining SNS will stimulate an equally long-term commitment to invest in U.S. by U.S. manufacturers.

ISEA applauds the groundwork laid for future SNS planning that would include a more comprehensive quantitative planning approach. **The SNS needs a centralized planning process that develops demand scenarios, prioritizes needs, and then establishes institutionalized supply solutions to meet those demands.**

Tax Credits for PPE

As Americans return to work, they are finding that the occupational safety landscape has fundamentally shifted. Many job categories that previously wore some type of respiratory protection, such as dentists, are returning to a workplace that now requires N95 respirators, and a large volume of them. Many more broad job types and categories that were never required to wear any type of protection are now being asked to wear a new category of protection, cloth face masks, that have not been widely used in the United States. Employers are installing a vast array of equipment to isolate workers safely. All of these solutions add up, and ISEA supports tax credits for employers to provide these solutions to their workers so that COVID–19 can be stopped in the workplace.

Non-medical fabric face-coverings are essential in every-day life during COVID–19. However, these items are not traditional PPE, and they are not sanitary products. **Therefore, ISEA asks that any legislation allowing for the deductibility of PPE and sanitary products specifically include non-medical machine-washable fabric face coverings as an item that would qualify for procurement tax deductions.**

As members of the Senate Finance Committee are likely aware, OSHA has published guidance stating cloth face coverings “[a]re not considered personal protective equipment (PPE).”⁶ But, OSHA also states in a related guidance that “. . . [e]mployers may choose to use cloth face coverings as a means of source control. . . .”⁷

A specific mention of cloth face masks will make certain employers can expense the costs of these devices, which limit the spread of SARS–CoV–2 and COVID–19. At the same time, maintaining that mention of cloth face masks as a separate item in the legislation, will allow the regulatory and safety community the time it needs to fully define this equipment and develop the practices around it that are needed to keep workers safe.

⁶ <https://www.osha.gov/SLTC/COVID-19/COVID-19-19-faq.html#cloth-face-coverings> (accessed July 10, 2020); see third bullet point. PPE is defined in the OSHA regulations at 29 CFR 1910.132.

⁷ <https://www.osha.gov/SLTC/COVID-19/COVID-19-19-faq.html#cloth-face-coverings> (accessed July 10, 2020); see second bullet point.

COSTS ASSOCIATED WITH OCCUPATIONAL SAFETY AND HEALTH TRAINING

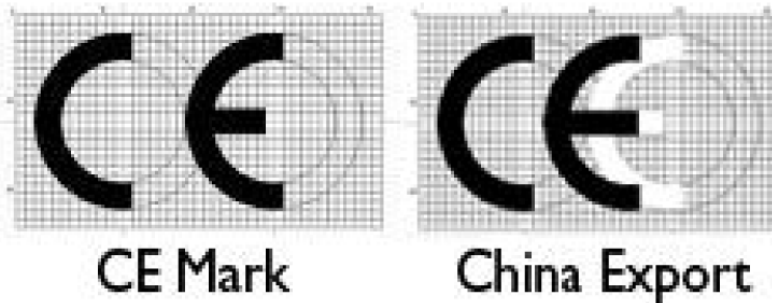
In addition, **ISEA asks that the Healthy Workplaces Tax Credit Act allow tax credits for costs of occupational health and safety training.** As Americans continue to work through COVID-19 and come back to work during COVID-19, keeping them safe is a national priority. Many employers are seeking to provide workplace health and safety training on topics such as: restructuring air flow for optimal safety; how to properly sanitize a workplace; how to conduct a user seal check on a respirator; how to take off (doff) gloves and other protective equipment in a safe manner that does not spread contamination; and more.

International Trade Agreements

ISEA asks that Congress urge U.S. Trade Representative Lighthizer to include in his trade discussions with the UK and the EU cooperative efforts to combat fake, fraudulently marked, and counterfeited products.

ISEA and members of this committee are no doubt aware the “China Export” mark is substantially similar to the official “CE” marking, which demonstrates a product has met the relevant and strict EU standards. This marking brings benefit to all in the supply chain and most notably, the consumer.

The “China Export” mark and only means that the product was manufactured in China. Here are the two markings:



ADD PROTECTIVE GLOVES AND GARMENTS INTO THE PREP ACT

The Public Readiness and Emergency Preparedness (PREP⁸) Act provides liability protection for items identified by the CDC as being essential to the response and mitigation of a public health emergency. Even though CDC recommends general-use gloves and garments to keep workers safe from harmful biological agents, these items are not included in the PREP Act.

In an outbreak of a novel infectious agent, such as COVID-19 or West African Ebola, the route of exposure and dose/response relationship is usually unknown. Also, in these instances, the Centers for Disease Control and Prevention (CDC) recommend, and end-users demand, general-industry personal protective equipment. This puts manufacturers and distributors at risk: provide the equipment and be exposed to opportunistic lawsuits or hold off from supplying equipment, which they wouldn't do because of ethics and commitment to national security.

ISEA asks Congress to meet PPE manufacturers and distributors half-way.

The current definitions in the PREP Act apply only to FDA-related devices, not the general industry types of gloves and garments often recommended by the CDC for worker protection during a public health emergency, including COVID-19. Public emergencies like outbreaks and pandemics frequently necessitate health care on an industrial scale that overwhelms the supply chains for normal medical (FDA approved) products. Most recently, in the COVID-19 pandemic, general industry

⁸The PREP Act is Division C of the Department of Defense, Emergency Supplemental Appropriations to Address the Hurricanes in the Gulf of Mexico and Pandemic Influenza Act, 2006 (Pub. L. 109-148).

gloves and garments are being used by hospital and medical personnel when “approved” supplies and stockpiles were depleted.

Addressing the PREP Act is vital. During the West Africa Ebola outbreak, CDC and other HHS officials recommended hospital workers use PPE not usually found in the health-care workplace, namely nitrile gloves and chemical protective garments. This created a great risk, because the government recognized these products, such as the types used in chemical plants, would be both effective and the best way to keep health-care workers safe. However, because these garments are designed for and used in environments that do not call for FDA registration or certifications, Federal authorities were unable to provide such devices with PREP Act protections due to the current definitions of what’s covered.

ISEA asks Congress to add a clear reference to gloves and garments directly to the PREP Act to mitigate this risk and make the PREP Act fair to all. Moving this issue through FDA only adds more regulatory uncertainty. ISEA would be grateful for your assistance in correcting this issue.

CONCLUSION

ISEA and its members are honored to be part of the solution that will see our workforce through the COVID-19 pandemic and better prepare the country for the next public emergency. We believe that a focus on the fundamentals of safety and health is the appropriate and necessary path forward.

- We must, as a Nation, plan better and on a larger scale for future emergencies.
- We must ensure that American responders have continued support from the world’s premier emergency response agencies for the selection and use of PPE.
- We must ensure the reliability and quality of the equipment provided.
- We must implement the public policy instruments that will ensure the supply of future equipment needs.

ISEA thanks the committee for this opportunity to testify.

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October 19, 2020

The Hon. Charles Grassley
Chairman
U.S. Senate
Committee on Finance
Washington, DC 20510

The Hon. Ron Wyden
Ranking Member
U.S. Senate
Committee on Finance
Washington, DC 20510

Re: Response to questions for the record from “Part 2: Protecting the Reliability of the U.S. Medical Supply Chain During the COVID-19 Pandemic”

Dear Senators Grassley and Wyden,

Thank you for inviting ISEA to testify at the Committee’s hearing: “Protecting the Reliability of the U.S. Medical Supply Chain During the COVID-19 Pandemic” held on Thursday, July 30th.

Attached please find ISEA’s answers to the questions for the record. Many questions asked for follow-up on ISEA’s comments about what can be done to improve data collection.

There are two answers here:

First, support the Office of the Strategic National Stockpile’s proposed “Next Gen SNS,” as described in a June 29, 2020 request for information.¹

Second, a near-term solution is to require the federal government (FEMA is the likely option given its current role in the COVID–19 response effort) to collect both PPE needs assessments of “emergency response providers” (as defined in 6 U.S.C. 101) and the amount of PPE such providers have on hand. This data must be collected in transparent manner.

When the needs and supplies-on-hand data are shared with manufacturers and distributors of PPE they can (1) structure plans to meet the demand and (2) assess level of federal assistance needed.

Below is proposed language to allow for this type of data collection and sharing to aid in the on-going COVID–19 response and mitigation effort. PPE will likely be needed by a number of those who did not need or use it before the pandemic.

Again, thank you. I can be reached at 703–525–1695 ext. 15 or at cjohnson@safetysupplyequipment.org if any Committee members or their staff members have additional questions.

Sincerely,

Charles D. “Chuck” Johnson, Jr.
President

ISEA AMENDMENT on DATA-GATHERING

New text in italic

Miscellaneous Statutory Provision that Relates to the Stafford Act

6 U.S.C. § 724. Logistics

(a) The Administrator shall develop an efficient, transparent, and flexible logistics system for procurement and delivery of goods and services necessary for an effective and timely response to natural disasters, acts of terrorism, and other man-made disasters and for realtime visibility of items at each point throughout the logistics system.

(b) *Reporting Requirements for an Emergency Involving Federal Primary Responsibility—Whenever the President issues a declaration for an Emergency Involving Federal Primary Responsibility (as defined in 42 U.S.C. 5191(b)) for a pandemic or public health emergency, the Administrator shall have the authority to collect information from emergency response providers (as defined in 6 U.S.C. § 101) on the amount of drugs, biological products (including vaccines), devices (including respiratory protective devices), and other medical supplies that are, or may become, critical supplies. To ensure the efficient and coordinated procurement, delivery, and distribution of such supplies by Federal agencies, private organizations, and state and local governments (as provided for in 42 U.S.C. 5192(a)(2)), such information shall be regularly updated to ensure realtime visibility on the amount and availability of these critical supplies at the state, local, and hospital levels.*

CROSS-REFERENCED INFORMATION

Highlights below are referenced in the red text above.

6 U.S.C. § 101—Definitions

(6) The term “**emergency response providers**” includes Federal, State, and local governmental and nongovernmental emergency public safety, fire, law enforcement, emergency response, emergency medical (including hospital emergency facilities), and related personnel, agencies, and authorities.

STAFFORD ACT: TITLE V—Emergency Assistance Programs

Sec. 501. Procedure for Declaration (42 U.S.C. 5191)

(a) Request and Declaration—All requests for a declaration by the President that an emergency exists shall be made by the Governor of the affected State. Such a

¹ https://beta.sam.gov/opp/d262bb77bb014a2cb422c8dc3ed0e636/view?keywords=75a50120nextgensns&sort=-relevance&index=opp&is_active=true&page=1

request shall be based on a finding that the situation is of such severity and magnitude that effective response is beyond the capabilities of the State and the affected local governments and that Federal assistance is necessary. As a part of such request, and as a prerequisite to emergency assistance under this Act, the Governor shall take appropriate action under State law and direct execution of the State's emergency plan. The Governor shall furnish information describing the State and local efforts and resources which have been or will be used to alleviate the emergency, and will define the type and extent of Federal aid required. Based upon such Governor's request, the President may declare that an emergency exists.

(b) **Certain Emergencies Involving Federal Primary Responsibility**—The President may exercise any authority vested in him by section 5192 of this title or section 5193 of this title [Sections 502 or 503] with respect to an emergency when he determines that an emergency exists for which the primary responsibility for response rests with the United States because the emergency involves a subject area for which, under the Constitution or laws of the United States, the United States exercises exclusive or preeminent responsibility and authority. In determining whether or not such an emergency exists, the President shall consult the Governor of any affected State, if practicable. The President's determination may be made without regard to subsection (a) of this section.

(c) **Indian Tribal Government Requests**—

- (1) **In General**—The Chief Executive of an affected Indian tribal government may submit a request for a declaration by the President that an emergency exists consistent with the requirements of subsection (a).
- (2) **References**—In implementing assistance authorized by the President under this subchapter in response to a request of the Chief Executive of an affected Indian tribal government for an emergency declaration, any reference in this subchapter or subchapter III (except sections 5153 and 5165d of this title [Sections 310 and 326]) to a State or the Governor of a State is deemed to refer to an affected Indian tribal government or the Chief Executive of an affected Indian tribal government, as appropriate.
- (3) **Savings Provision**—Nothing in this subsection shall prohibit an Indian tribal government from receiving assistance under this subchapter through a declaration made by the President at the request of a State under subsection (a) if the President does not make a declaration under this subsection for the same incident.

Sec. 502. Federal Emergency Assistance (42 U.S.C. 5192)

(a) **Specified**—In any emergency, the President may

- (1) direct any Federal agency, with or without reimbursement, to utilize its authorities and the resources granted to it under Federal law (including personnel, equipment, supplies, facilities, and managerial, technical and advisory services) in support of State and local emergency assistance efforts to save lives, protect property and public health and safety, and lessen or avert the threat of a catastrophe, including precautionary evacuations;
- (2) coordinate all disaster relief assistance (including voluntary assistance) provided by Federal agencies, private organizations, and State and local governments;
- (3) provide technical and advisory assistance to affected State and local governments for—
 - (A) the performance of essential community services;
 - (B) issuance of warnings of risks or hazards;
 - (C) public health and safety information, including dissemination of such information;
 - (D) provision of health and safety measures; and
 - (E) management, control, and reduction of immediate threats to public health and safety;
- (4) provide emergency assistance through Federal agencies;
- (5) remove debris in accordance with the terms and conditions of section 5173 of this title [Section 407];
- (6) provide assistance in accordance with section 5174 of this title [Section 408];

(7) assist State and local governments in the distribution of medicine, food, and other consumable supplies, and emergency assistance; and

(8) provide accelerated Federal assistance and Federal support where necessary to save lives, prevent human suffering, or mitigate severe damage, which may be provided in the absence of a specific request and in which case the President—

(A) shall, to the fullest extent practicable, promptly notify and coordinate with a State in which such assistance or support is provided; and

(B) shall not, in notifying and coordinating with a State under subparagraph (A), delay or impede the rapid deployment, use, and distribution of critical resources to victims of an emergency.

(b) General—Whenever the Federal assistance provided under subsection (a) of this section with respect to an emergency is inadequate, the President may also provide assistance with respect to efforts to save lives, protect property and public health and safety, and lessen or avert the threat of a catastrophe, including precautionary evacuations.

(c) Guidelines—The President shall promulgate and maintain guidelines to assist Governors in requesting the declaration of an emergency in advance of a natural or man-made disaster (including for the purpose of seeking assistance with special needs and other evacuation efforts) under this section by defining the types of assistance available to affected States and the circumstances under which such requests are likely to be approved.

QUESTIONS SUBMITTED FOR THE RECORD TO CHARLES JOHNSON

QUESTIONS SUBMITTED BY HON. JOHN THUNE

Question. In your written testimony you mention how sellers of counterfeit products have leveraged online platforms like Amazon to gain access to unsuspecting consumers. I recently introduced the bipartisan Platform Accountability and Consumer Transparency Act, or PACT Act, which would help ensure that online platforms are liable if they do not remove content or stop activity that a court order found to be unlawful. Do you believe this could help incentivize action by tech companies to stop the sale of illegal PPE on their sites?

Answer. The PACT Act's provisions to: (1) require technology platforms to have an individual, who can be reached to hear complaints about fake and fraudulent products being offered on the particular technology platform and (2) remove from the 1934 Communications Act's liability protections if quick action is not taken would seem to incentivize online platforms to take quick action on legitimate complaints and could provide incentive for platforms to take preemptive actions and consider the legitimacy of products before they are accepted on to the platform.

Question. You and other witnesses testified regarding the "just-in-time" approach to supply procurement. As I understand it, health systems have optimized inventory management to keep costs low. I expect the same is true for the manufacturers you represent in terms of the need to find efficiencies. As we are looking for ways to improve preparedness for future emergencies, how do we ensure we are investing in domestic manufacturing capabilities prudently given the need to also be cost-competitive?

Answer. There are multiple ways to ensure we are investing in domestic manufacturing capabilities prudently which take into account the need to also be cost-competitive. One is for HHS to have its own grant making authority, similar to title III of the DPA that could be used to prepare when the Nation is not under a declared emergency order. Recent reports show that DoD has contracted with companies that have not been able to deliver needed products. HHS is familiar with the products used by healthcare professionals and the known and trusted suppliers of these products. A second option is a revolving stockpile model. This would allow manufacturers and their distributors to work cooperatively with end-users. In this situation, the distributor is authorized to sell a certain percentage of the product that manufacturer will then replenish. This type of vendor-managed inventory has been discussed, but we have not seen this type of contractual arrangement yet for personal protective equipment (PPE) for a public health emergency.

Both options, and other possible inventory and stockpile solutions, should be implemented in a manner to fully price in emergency preparedness to the existing PPE

supply chain. Just-in-time supply provision guarantees that the size and capability of manufacturing and distribution will adjust to the existing market. Emergency preparedness must, in the future, be a known, quantified and resourced part of that market.

QUESTIONS SUBMITTED BY HON. RON WYDEN

Question. During your testimony, you stated that additional data collection is needed to improve the distribution of personal protective equipment to medical facilities in rural and underserved communities, including black, indigenous, Latinx, and communities of color. Please be as specific as possible about the types of data the Federal government should be collecting and disseminating to facilitate the distribution of PPE? How would the industry use this data to improve distribution of PPE to these communities?

Answer. The types of data the Federal Government should be collecting from emergency response providers, as defined in 6 U.S.C. § 101 (see citation below), and in turn disseminating to manufacturers and suppliers of general use and medical PPE includes: (1) the amount on-hand of drugs, biological products (including vaccines), devices (including respiratory protective devices), and other medical supplies that are, or may become, critical supplies; and (2) 30-, 60-, and 90-day demand projections these critical materials.

ISEA believes that WITH such information, for which the association has been calling on the Federal Government, manufacturers and distributors can provide needed PPE where and when it is needed, including to underserved communities.

6 U.S.C. § 101

(6) The term “**emergency response providers**” includes Federal, State, and local governmental and nongovernmental emergency public safety, fire, law enforcement, emergency response, emergency medical (including hospital emergency facilities), and related personnel, agencies, and authorities.

Question. The Trump administration has relied on the practice of reusing PPE to make it look like there are adequate supplies at hospitals and other medical settings, which has been a big safety concern for workers. The American Nurses Association surveyed 14,000 nurses in May and found that 45 percent worked at facilities with shortages of PPE, and 79 percent reported having to reuse PPE. In July, the National Nurses Union released a survey of 21,000 nurses, of which 87 percent reported re-using PPE. My staff heard similar stories from around the country. One nurse in Houston, where the virus is surging, told minority staff that her hospital is cleaning and reusing N95 masks up to 10 times. When PPE like N95 respirators or surgical masks are manufactured, are they intended to be used a single time?

Answer. Filtering facepiece respirators, including N95s, are designed, certified, and manufactured as disposable products. However, it does not mean that during an emergency they cannot be re-used. But still, it is not considered a best practice. Even before the Severe Acute Respiratory Syndrome (SARS), the National Institute for Occupational Safety and Health (NIOSH) had in place recommendations for reuse of disposable respirators in emergency situations. These recommendations can be found here.¹

Question. What steps should the Federal Government take to secure adequate PPE supplies?

Answer. There are multiple ways to secure adequate PPE supplies. One is for HHS to have its own grant making authority. (Recent news stories show DOD has contracted with companies that have not been able to deliver needed products.) HHS is familiar with the products used by healthcare professionals and the known and trusted suppliers of these products. A second option could be a combined program with manufacturers and their distributors whereby a long-term Federal contract allows a distributor maintain PPE supplies for the Federal Government but still able to sell a certain percentage of the product (first in, first out) that a manufacturer will then replenish. This type of vendor-managed inventory has been discussed, but we have not seen this type of contractual arrangement yet for personal protective equipment (PPE) for a public health emergency.

¹<https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html>.

These and other programs must continue to be a focus of Federal policy and allocation even after the COVID-19 pandemic has passed. The best emergency response can be hampered by a lack of preparedness, and history has shown the best preparedness programs are only as effective as their funding levels allow.

Question. The Trump administration testified in July that it has used the Defense Production Act “more than 10 times” to combat COVID-19, an extraordinarily narrow use of existing authority that stands in stark contrast to Federal agencies historical use of DPA. Historically, the statute has been used to acquire supplies and services in times of emergency and in day-to-day business. For example, the Department of Defense places approximately 300,000 rated orders annually, while the Department of Homeland Security, including FEMA, placed more than 1,000 rated orders and contracts in 2018. Specific examples include using priority orders to acquire the Adenovirus vaccine, expediting construction of floodwater controls in New Orleans, speeding up the purchase of railroad equipment following Hurricane Katrina, and obtaining resources needed to house and feed disaster survivors and first responders, communications equipment and information technology needs, and other logistical needs supporting disaster response and recovery efforts. Given the shortages of PPE you have experienced, shouldn’t the administration use the Defense Production Act to increase the availability of personal protective equipment and better allocate supplies?

Answer. ISEA is pleased to see attention to allocating supplies. As noted in our answer to your first question, a structured, uniformly implemented data gathering program will allow for optimal allocation of PPE and other critical supplies for public health emergency response. Regarding the first part of the question, the government did use the Defense Production Act with industry in 35 instances.² The DPA is most effective when used *cooperatively* with industry. ISEA stresses the cooperative aspect of this because in one case, the DPA was used to help an automotive company build powered air purifying respirators (PAPRs), but that action *flowed down*, which meant an existing PAPR manufacturer was no longer able to get a critical component for its PAPR. ISEA understands the issue was resolved, but not without delay in production of this important COVID-19 product.

In addition, FEMA, which in April was given authority to use powers under DPA, is now using title VII of the Act to structure voluntary agreements to allow a wide array of Federal agencies, companies and associations to share detailed data to optimize public health emergency response

Question. The CARES Act included funding for title III of the Defense Production Act. How much of that funding has been allocated to members of your industry? What projects has it been used for? How many applications do your members have pending? Would your members have an appetite for additional title III funds in future legislation?

Answer. Certainly, ISEA members would welcome additional DPA funds for pandemic response PPE. The DPA agreements are one tool the government can employ to price preparedness into the supply chain. By entering onto long term contracts for PPE supplies, the government can work cooperatively with the private sector to prepare for future events. These agreements would be maximally efficient when used to help existing PPE manufacturers increase capacity. Finally, the association believes that an HHS-funded grant-making program that can continue the DPA’s mission once the public health emergency declaration is lifted can serve to help fill Federal, State, and local emergency pandemic stockpiles.

As noted above, ISEA members welcome a cooperative approach to use of the DPA. In addition, as noted in the answer to Question 3, ISEA understands other legislation may be introduced to provide HHS with similar grantmaking authority. Because HHS has greater familiarity with the end-users and manufacturers of PPE used by healthcare workers, this agency may be in a better position to make grants for acquisitions of PPE.

QUESTION SUBMITTED BY HON. MARIA CANTWELL

Question. In my State, health-care workers are reporting a noticeable decline in the quality of PPE available to them.

² <https://www.whitehouse.gov/wp-content/uploads/2020/08/OTMP-DPA-Report-FINAL-8.13.20.pdf>.

I spoke with a cancer care nurse from Swedish Hospital in Seattle who said that she and her colleagues are forced to reuse the PAPR hoods in the hospital to the point that they are being held together by duct tape.

Is it safe for our nurses and doctors who are on the front lines responding to a global pandemic to be reusing PAPR hoods until they are falling apart?

Answer. Powered Air Purifying Respirators (PAPRs) are key aspect of public health emergency response, and should be part of the strategic national stockpile. This way, health-care providers that use these could be supported the by SNS.

Like other types of personal protective equipment (PPE), safety managers should follow manufacturers instruction on use. Generally, these calls for inspection of the product before and after each use.

More generally, one of ISEA's core mission objectives is to ensure the safety and function of PPE that is marketed in the United States. This includes support for the proper use of PPE. In that regard, we support PPE standardization and conformity, use in accordance with manufacturers' guidance and labeling, and adherence to the recommendations of public health and safety agencies.

QUESTION SUBMITTED BY HON. DEBBIE STABENOW

Question. Senator Casey mentioned the need to innovate on PPE for health-care workers as we respond to this pandemic and prepare for the future, an effort I am proud to work with him on.

What innovations do you see as the most critical to be able to better respond to pandemics in the future, and how can Congress and the administration encourage and support such innovation?

Answer. Safety equipment manufacturers are constantly working to design new, improved safety products that are easy to use and comfortable to wear. NIOSH's certification level of 95-percent filtration efficiency is a backstop for worker safety and not a regulatory barrier.

Most innovation in respiratory protection is in reusable respirators. Congress might consider a program, where healthcare providers are incentivized to use reusable respirators in addition to disposable respirators. In these respirator classes, there are many new designs, technologies and features. A grant program to help speed up these technological advances could be considered.

Congress should consider a mandate to NIOSH to update its standard test protocols (STPs), which act as unofficial regulations. NIOSH has voluntarily begun working with manufacturers to update the STPs, removing unneeded and redundant tests and requirements. The STPs are equal to NIOSH regulations in the certification process. A benefit to the structure of the STPs is that if a new test technology becomes available, it is easier to add that to the STPs than it would be to add such a new testing technology to a regulation if the STPs were codified.

Congress should provide funding for NIOSH. This agency has served a critical role for the Nation during the pandemic. The National Personal Protective Technologies Lab, which certifies respirators, is based in Bruceton, PA, at an old Bureau of Mines facility. Funding is needed for both buildings and to modernize the facility's test labs (some test labs on the NPPTL site are located in corrugated steel structures), and to increase in the Lab's personnel count. Both would help speed-up the certification process and boost the Nation's ability to respond to and mitigate future public health emergencies.

QUESTION SUBMITTED BY HON. SHELDON WHITEHOUSE

Question. Like many states, Rhode Island has had chilling experiences procuring PPE, including unfulfilled orders, fraudulent sales, and a competitive race for supplies. This toxic atmosphere discourages not only buyers, but also suppliers, from entering the PPE market, as manufacturers face challenges understanding the market, product standards, and the allocation process. In your experience as buyers of PPE on behalf of hospitals and health-care providers, what does the current PPE market look like and how has it been tainted by the disorganized, toxic procurement process?

Answer. While ISEA does not buy PPE for hospitals, the disorganized, toxic procurement process has two impacts on legitimate PPE manufacturers: (1) respirator, protective garment, and glove manufacturers have had to increase their awareness of their brands and company identity being ripped off; and (2) these PPE manufacturers have had to inform and educate end-users about how to be aware of fake websites.

NIOSH has provided a useful service of testing the filtration efficiency of non-NIOSH foreign made respiratory protective devices. This allowed some large, institutional buyers to know that (1) a foreign company was legitimate if it was willing to send samples for testing in the U.S. by a Federal agency and (2) the results helped purchasers make informed decisions.

As we have noted in responses to other questions from members of the Senate Finance Committee, use of the Defense Production Act, or in the future, of grant making program at HHS or other Federal agencies, would aid in availability of product.

The current leadership and staff members of the office of the strategic national stockpile proposed in June, their "Next Gen SNS." ISEA believes this proposal will bring rationality, complete data awareness and optimization for future public health emergency response activities. ISEA also offers suggestions to bring rational, data-driven decision making to public health emergency response in our answer to Senator Wyden's first question.

One complicating factor has been rated orders. Given the Federal contracting process, a number of small firms presented significant orders to manufacturers. Understanding which orders were legitimate and which were not took time to figure out.

QUESTIONS SUBMITTED BY HON. CATHERINE CORTEZ MASTO

Question. In your testimony, you noted that investments made under title III of the Defense Production Act are helpful to increasing supply. What kind of investment would Congress need to make in title III DPA authorities in order to ensure that there is sufficient supply of PPE to meet demand?

Answer. ISEA believes the data gathering discussed above, where by the Federal Government assesses what emergency response providers (again, as defined at 6 U.S.C. §101: Federal, State, and local governmental and nongovernmental emergency public safety, fire, law enforcement, emergency response, emergency medical (including hospital emergency facilities), and related personnel, agencies, and authorities) have on hand and will need in the foreseeable future, combined with data from DoD's use of the DPA for PPE, will provide the answer.

Question. Several of the witnesses on the panel discussed the importance of greater transparency in the supply chain to make sure that manufacturers have an accurate picture of need, and providers know what they're getting and when they're getting it. What should Congress be doing at the Federal level to facilitate that? What entity should be charged with producing and making available the information that you need?

Answer. Congress can provide FEMA with the immediate authority and congressional mandate to collect in a transparent manner data from "emergency response providers" as defined in 6 U.S.C. 101. This data should be shared with manufacturers of products needed to mitigate and respond to the pandemic, who can use that to help plan on-going production. ISEA asks this because there is immediate need for this data, which will likely continue over the next few years.

PREPARED STATEMENT OF ROBERT J. WIEHE, SENIOR VICE PRESIDENT AND
CHIEF SUPPLY CHAIN AND LOGISTICS OFFICER, UC HEALTH

Chairman Grassley, Ranking Member Wyden, and distinguished members of the committee, thank you for the opportunity to speak with you today on a matter of utmost importance to the country: protecting the reliability of the U.S. medical supply chain.

As the senior vice president and 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 health-care 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 health-care 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 are facing in today's environment.

Our president and CEO, Dr. Rick Lofgren, is one of three health executives in Ohio serving in an advisory capacity to Governor DeWine on Ohio's response to the COVID-19 pandemic. With leadership from State executives and the Ohio Hospital Association, the State created geographic regions in order to have a coordinated, regional approach to the pandemic. This geographic coordination, that includes active participation and engagement from regional and local leaders and public health experts, has created an environment of partnership and cooperation oftentimes not seen between hospitals or between hospitals and public health. Through these communication pathways, we have been able to quickly identify and resolve barriers and challenges—oftentimes using unique and innovative solutions.

One such innovative solution is the "Virtual Stockpile," created by the Ohio Hospital Association in partnership with Governor DeWine, to guarantee that the hospital industry would contribute supplies to congregate living facilities, rural hospitals, health clinics, etc. so that Ohio's economy could open, and remain open. The Ohio Hospital Association coordinates this effort on behalf of their membership and, while it is in its infancy, shows the promise of what true collaboration could look like during any disruption to the medical supply chain.

In my role, I have participated in State-level conversations about the reliability of the supply chain, partnered with other academic and community hospitals to leverage the supply chain on State, regional and local levels, and coordinated an aggressive internal strategy to access supplies directly for our care teams and patients.

Today, I will provide a brief overview and background on health-care supply chains. I will also highlight challenges, lessons learned and potential resulting strategies for moving forward post COVID-19. For each of these areas, I will segment my comments by focusing on perspectives from both the Demand side and Supply side. Lastly, I will provide a summary of the impact that COVID-19 has had on our health-care system and provide potential areas of improvement to the committee based on my insights and experiences in over 30 years in Operations and Supply Chain Management.

HEALTH-CARE SUPPLY CHAIN BACKGROUND AND OVERVIEW

Traditional health-care supply chains were typically transactional-based departments which were focused on purchasing and distributing materials within the hospital or system. In recent years, as reimbursement models have shifted towards value based, patient centered care the hospital supply chain has shifted its focus and become more strategic and integrated with its clinical partners. Supplies are often the second largest expense within a health-care system, accounting for anywhere from 25 percent to 35 percent of total expenses—labor is the only category that is larger than supply expense. Value based reimbursement systems reward providers who decrease costs while improving quality and outcomes, creating an improved and more cost-effective system.

This change has shifted the focus of supply chain executives from transactional to an integrated model with a laser focus on Cost, Quality and Outcomes (CQO). This focus has forced better alignment with internal customers and led to improvements in cost, quality and outcomes through efforts such as product standardization. These efforts required improvements in infrastructure and systems that integrate pure purchasing data such as quantities and price with quality, outcomes and utilization patterns. Improved data capabilities have enabled physicians, clinicians and supply chain to start align purchasing decisions thereby driving improvements in CQO. Not all health-care systems are fully integrated, but the vast majority are moving in this direction in order to more deeply understand demand, reduce waste, improve outcomes, and lower the overall cost of health care.

Hospital supply chains differ from their industry counterparts in that they are much more reliant on Group Purchasing Organizations (GPOs) and Prime Distribu-

tors to assist with day-to-day activities. Even with the most rigorous standardization efforts, many systems still have thousands of parts they are trying to contract, purchase, inventory and distribute. The sheer magnitude of this number of products often necessitate the use of these strategic third party partners to assist with contracting, purchasing and distributing of materials for health systems. In fact, many systems are looking towards these strategic partners to help drive costs out of the internal health care supply chain. Examples of this include the utilization of GPO price contracts to eliminate the need for local contracting and utilizing prime distributors and converting to a just-in-time (JIT) delivery model which eliminates the need for bulk warehousing and storage onsite.

While health-care supply chains have become increasingly efficient in helping to drive out cost and inefficiencies, they have also become heavily inward focused. The use of strategic vendors to perform critical functions can be a very cost-effective approach, however, it adds another layer or touchpoint within the overall supply chain and can lead to neglect and a lack of understanding into where there may be supply risks upstream. The lack of integrated systems or tools to help track utilization and forecast demand also impacts the overall supply chain and its ability to quickly react to changes.

HEALTH-CARE SUPPLY CHAIN CHALLENGES

Demand

1. The increased demand spike for COVID–19-related medical supplies was unprecedented. Demand for supplies such as PPE, testing equipment, testing supplies, ventilators, physical plant resources (monitors, beds), and ventilator-related drugs started to climb in March.
2. Low-volume products, such as PPE, became high-volume overnight. Allocations from prime distributors were based on historically low usage of these supplies, thus allocated supply was inadequate to meet health-care system needs.
3. Unknown usage and shifting usage patterns caused anxiety and stockpiling of supplies as they were available.
4. The increase in demand spike for certain essential drugs with increased off label use stressed areas within the pharmaceutical supply chain.
5. An increase in demand from non-traditional customers such as first responders, nursing homes and others contributed to the rapid increase in demand for PPE products worldwide.

Supply

1. A large percentage of manufacturing capabilities for both raw materials and manufacturing are located in the Asia-Pacific region. This includes both PPE and a large number of Active Pharmaceutical Ingredients (API's) required for many medicines and drugs.
2. Existing manufacturing facilities around the world were disrupted due to closures and lockdowns to prevent the spread of COVID–19.
3. Export restrictions were imposed by many countries to protect domestic supplies during the height of the crisis.
4. Distribution and logistics capacity constraints were affected by workforce issues. Sickness and travel bans have had an effect on commercial air and ocean freight carriers. Many suppliers were chartering private planes to help expedite shipments.
5. There was a significant increase in counterfeit PPE products and gray market suppliers.
6. A lack of transparency and communication across the medical supply chain network slowed and confused responses from health systems.
7. The global impact of COVID–19 was unparalleled. In a more typical disaster, such as a hurricane, supply chains can redirect resources from one geography to another. The global impact of this pandemic did not allow for shifting of resources—all areas were hit equally throughout the world.

HEALTH-CARE SUPPLY CHAIN LESSONS LEARNED AND RESPONDING STRATEGIES

Demand

1. Implementing preservation and reuse policies, to protect and preserve limited supply resources, were a necessity. A great deal of effort went into preservation policies with strong collaboration between health-care providers, infection control and supply chain leaders. All efforts were coordinated to ensure health-care workers were protected while trying to preserve supplies in the face of scarcity.
2. New businesses were created to assist with the shortage of supplies. Decontamination efforts for N95 masks were fast tracked. Battelle in Columbus, OH was granted the approval by the FDA and awarded a contract by HHS and FEMA and funded up to \$400 million to assist health-care facilities with decontamination of masks.
3. Innovation labs were mobilized quickly at universities like the University of Cincinnati to research and look for alternative solutions to supply issues. 3D printing of masks, swabs, and respirators were among the first innovations that were presented to health-care systems. Additionally, innovative solutions to re-tool and re-use non-standard equipment was also at the forefront of innovation.
4. Data collection and reporting on daily PPE usage (by department and site) was critical to monitor demand spikes and to ensure that preservation efforts were being followed.
5. Local and State organizations (*e.g.*, Ohio Hospital Association) mobilized and helped to facilitate dialogue and solution sharing among members.
6. Strong collaboration and communication networks between health systems has become commonplace. Sharing of ideas and supplies has become standard practice as everyone is learning and adapting to this pandemic.

Supply

1. Production expansion with existing traditional manufacturers quickly increased but was also insufficient to meet increased demand. Companies such as 3M and Medline quickly ramped up production worldwide at existing manufacturing facilities.
2. Modification of existing production lines to run additional or new product was also enabled as quickly as possible to increase output of much needed supplies.
3. Extended hours of operation and overtime was used wherever possible to increase output in existing manufacturing facilities.
4. Nontraditional manufacturers entered the space quickly to assist the country with the need for PPE. Athletic and apparel companies were among many who quickly pivoted operations to assist with products like protective eyewear and simple masks. Procter and Gamble is an example of a Cincinnati company who quickly pivoted operations to manufacture critical supplies and donate to local and regional health systems.
5. In addition to the university 3D printing efforts, industry 3D printing leaders also quickly looked for ways to partner with universities to find expedited solutions that worked for the medical community.
6. Many companies also pivoted to make ventilators, however, retooling manufacturing lines in addition to longer lead times for this type of manufactured equipment did not provide immediate relief.
7. Sourcing expansion of both raw materials and finished products happened quickly from both the supplier and customer side of the equation. Suppliers were looking for alternative solutions to meet the increased need while end users were looking to source product from non-standard suppliers in order to secure product as quickly as possible.
8. Supply Chain transparency platforms have been created to assist with communication across entire supply chains. Vizient and One Network Enterprises are a great example of this much needed improvement in the U.S. medical supply chain.
9. Logistics providers partnered with both the private sector and the government to expedite shipments and increase logistics service capacity.

10. Supply allocation was quickly put in place by domestic manufacturers and distributors alike, thus ensuring that products were available for “hotspots” that were hit the hardest.
11. From a global perspective, export restrictions were put in place to keep scarce medical resources in the United States.

UC HEALTH—FISCAL IMPACT

The unanticipated health-care supply chain costs due to COVID-19 have been staggering; the long-term impact to the U.S. health-care system remains to be seen. With the prohibition on elective procedures, the impact of COVID-19 from a fiscal perspective was a loss of approximately \$110 million in April/May. This represents a 5–6 percent loss of total annual revenue over this 2-month period. Expenses during this same period increased by approximately \$10 million largely due to buildup of inventories for PPE.

While hospitals are no longer prohibited from providing elective procedures for patients, FY21–22 will continue to see an increase in expenses and overall reduced revenue for the system. Expenses will continue to be larger than historical levels due to many new developments as a result of COVID-19. A few examples include increased utilization of supplies, new expenses such as screening stations at hospital entrances, increased lab testing, and investment in additional infrastructure such as telehealth. This increased utilization of supplies is coupled with higher than normal pricing. The chart below provides data on a small sample of UC Health PPE utilization and pricing (Pre-COVID and current):

	Pre-COVID-19		COVID-19		Average Price		
	Avg. Daily Usage	Avg. Price (ea.)	Avg. Daily Usage	Max. Price (ea.)	April	May	June
Exam Glove	9,405	\$0.06	47,876	\$0.06	\$0.06	\$0.06	\$0.06
Impervious Plastic Gown	2,886	\$0.27	5,996	\$2.34	\$1.20	\$2.30	\$0.32
Level 1 Mask	2,280	\$0.11	8,343	\$1.95	\$1.12	\$0.06	\$0.07
N95 Mask	159	\$0.64	382	\$6.50	\$3.21	\$1.69	\$1.50
Face Shield	52	\$0.96	128	\$6.00	\$3.65	\$0.96	\$0.96

UC HEALTH—SUPPLY CHAIN IMPACT AND EXPERIENCES

Demand

While southwest Ohio was not an initial hotspot, and that allowed us the benefit of learning from others, it also meant that the region was not prioritized in terms of obtaining limited resources. As resources were distributed to national hotspot areas, we often needed to engage our elected leaders to intervene on our behalf with Federal leaders and/or the manufacturer in order to obtain the items we needed to provide a stable and ongoing COVID-19 response in southwest Ohio.

We view the current medical supply chain (from PPE to testing supplies to machinery) as “comfortable, not confident,” and we continue to advocate for a national and State distribution strategy (public and private) that allows resources to be distributed to all geographic areas.

As a standing member of our Incident Command Center, collaboration between clinical leaders, infection control and supply chain was vital to developing a plan and understanding what future demand for critical supplies would look like. Broad communication of appropriate PPE use, re-use and storage was a critical component that helped supply chain to better understand and develop a strategy for sourcing these scarce resources. Collaborative planning helped to provide appropriate protection to UC Health employees while ensuring that usage data was collected and monitored on a daily basis. Daily reports from Supply Chain helped to alleviate clinical concerns about the supply of PPE for the system. All sourcing decisions and activities were centralized and supplies were strategically placed in work areas with nursing leaders playing a vital role in monitoring and dispensing as appropriate. These interventions did not happen overnight, but constant communication between

all parties helped facilitate a better understanding and less fear among all stakeholders.

Supply

With critical supply on allocation from our prime distributor due to their inability to meet demand, UC Health had to quickly pivot and source PPE from non-standard suppliers. This change in activity was dramatic and shifted from a supply that was on automatic replenishment with one vendor to reaching out and making over 500 new sourcing inquiries in a 30–45 day period to vendors we had no prior experience with. This presented a unique challenge with respect to balancing the urgent need for product and the inherent risk in dealing with unknown third parties. UC Health relied on a strong network of contacts and collaboration with peer academic medical centers across the country to work with credible vendors and weed out bad actors.

UC Health's strategy was to focus on known or existing vendors and, if at all possible, to steer clear of new vendors entering the market. We mitigated risk by spreading multiple smaller orders through various vendors versus trying to rely on singular large purchases to cover all of our needs. The vendors we utilized were already in the business of supplying either the health-care industry in another capacity or a different industry in a similar capacity. For example, we used a vendor who had previously focused on supplying material handling bins to the health-care industry, but was able to utilize their network of logistics and suppliers to quickly enter the PPE space. Another vendor we found supplied PPE into a different industry than health care but was able to pivot and start selling industrial respirators into health care as the CDC and NIOSH released expanded lists of approved N95 masks. As UC Health and others started to have success with non-standard vendors, we quickly shared successes with our counterparts to build an alternative supply network.

In southwest Ohio, there was tremendous cooperation among health systems and even some attempts to combine our purchasing power and look for large scale opportunities to purchase simple masks and N95 masks. While I believe there eventually was some limited success with this approach, we learned that there were many scams and promises of large quantities of supplies coming in from outside the United States. These scams involved large sums of money being placed in escrow or cash in advance purchases for goods that did not materialize. UC Health relied on our internal legal team to vet potential sellers and was fortunate that we did not lose any money despite our involvement, albeit limited, with some of these transactions. UC Health quickly moved away from this approach and continued to place smaller orders with more reliable vendors.

Product Vetting

A majority of the product we successfully sourced came from China or other Asian-Pacific countries. A great deal of time and resources were spent vetting these products before we moved forward with purchasing. Our standard approach required a potential vendor to submit material specification sheets, FDA Certificates of Approval, Third Party Testing Certification and samples that were reviewed by our infection control team. A significant percentage of the information we reviewed did not prove to be authentic. FDA certificates were submitted that did not match what we could find online at the FDA website and third-party testing certificates were submitted that could not be verified. If a product made it past these initial checkpoints, our team then tested the product to ensure that all materials received matched specification sheets. Using the methodology described above, UC Health was fortunate that we did not purchase or receive any non-standard or counterfeit products.

Supplier Communications

During the initial months of the pandemic, UC Health had several shipments delayed and our suppliers communicated to us that this was due to the supplies being either purchased or seized by the Federal Government. Shipments were often delayed for 2–4 weeks until another shipment arrived from overseas. In order to circumvent product being held or seized at the port of entry, our suppliers communicated that they were labeling packages as “not for medical use.” We received product labeled as such and they met all specifications and testing criteria. We were not direct recipients of this communication from the manufacturer and can only attest to what we were told by our suppliers.

Another frequent communication from our suppliers in the first 4–6 weeks of the pandemic was the inability to get shipments into the country due to the lack of available capacity with commercial air freight companies. Suppliers used multiple

methods of transport to overcome this constraint including private charters, smaller and more numerous shipments on Fed Ex or UPS, and ocean freight, which delayed availability by 2–4 weeks.

Regional and Strategic National Stockpile Assistance

Starting in February, 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 health-care providers, EMS, law enforcement and hospitals through EMA request processes.

In early March, 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.

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, health-care leaders, and industry leaders from the non-health-care 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 health-care industry, I would offer the following specific examples of areas that can continue to be strengthened and improved:

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 health-care supply chain to help facilitate these efforts.
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 days 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.
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 26th, U.S. 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 U.S. and Mexico is 65 million masks.

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 health-care 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 health-care 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 health-care supply chain from end to end and create greater transparency and resiliency in the process.

I am happy to answer any questions from the committee.

PREPARED STATEMENT OF HON. RON WYDEN,
A U.S. SENATOR FROM OREGON

The Finance Committee is focusing this week on issues dealing with the lack of high-quality PPE and other equipment during the pandemic.

I know that the other side would like this to be all about China, China, China, and I agree that counterfeiting is a problem. But if you're focused entirely on that aspect of the issue, you're skipping right past the bigger story, which is the Trump administration's casual disinterest in leadership when it comes to getting PPE and making sure our health-care heroes are equipped. It goes back even before the pandemic began.

In 2019, the Federal Government conducted a pandemic war game called "Crimson Contagion." In it, a hypothetical airborne virus originated in China and made its way to the U.S., infecting 110 million people and killing nearly 600,000. The exercise concluded the U.S. would need 3.5 billion N95 masks to fight a large-scale pandemic. The Trump administration took no action to acquire them. The coronavirus arrived just a few months later.

On March 19, 2020, with coronavirus cases beginning to go skyward, the President said the following when asked about buying and distributing PPE: "The Federal Government's not supposed to be out there buying vast amounts of items and then shipping . . . Governors are supposed to be doing it."

On March 29th, he accused nurses and doctors of stealing PPE: "Something is going on, and you ought to look into it as reporters. Where are the masks going? Are they going out the back door?"

In mid-April, he called reports of PPE shortages "fake news."

On May 6th, a nurse told reporters gathered in the Oval Office that the availability of PPE was "sporadic." Trump responded, quote, "Sporadic for you, but not sporadic for a lot of other people. . . . I have heard we have a tremendous supply to almost all places."

Just last week, he said, "My administration currently has zero unfilled requests for equipment or anything else that they need from the Governors . . . frankly we are stocked up and ready to go."

Wrong, wrong, wrong.

Just in the last few days, Democratic Finance Committee staff have gathered direct accounts from health-care workers about PPE shortages that are devastating communities, given the recent spikes in cases. The committee heard from nurses in Dallas, TX, where COVID cases are surging, who recently began buying their own surgical masks since their hospital was requiring staff to reuse old ones for days at a time.

The committee heard from an administrator of a 33-bed hospital in rural Alabama, serving a majority black community, who told the committee her hospital is so low on PPE that she keeps an emergency supply stashed in her office for safe-keeping.

One Oregon home health-care nurse, who didn't want to provide their name for fear of retribution from their employer, told the committee they have so few disinfectant wipes that they are cutting them in quarters to last through the week.

Finance Committee Democrats want to make sure these important stories are still being heard. So I encourage doctors and nurses and first responders and nursing

home staff dealing with shortages and defective equipment to submit personal stories for the hearing record at PPEshortages@finance.senate.gov. If we've learned one thing, it's that getting these stories into public view and in front of Senators can make a lot of difference.

This week, the National Nurses Union released a survey of 21,000 hospital nurses. Eighty-seven percent reported having to reuse PPE that's designed for a single use. According to CDC data, hundreds of nursing homes didn't have PPE in mid-July, and thousands more had less than a week's supply. States like Oregon, cities, and health-care providers have been forced to compete against each other and pay ransoms for equipment on the open market. That has opened the door to junk sold by scam artists and incompetent vendors.

A group of health systems was so concerned about losing access to PPE that it recently bought a minority stake in a big PPE manufacturer to keep the pipeline open. What about the smaller hospitals and independent doctor's offices and nursing homes that can't afford to buy their own manufacturers?

The Trump administration has touted Jared Kushner's Project Air Bridge as a PPE game changer, but Project Air Bridge brought in just 4.5 million N95 masks over the course of 3 months this spring. HHS's own estimates said the U.S. needed 300 million N95 respirators every month.

The fact is these shortages of PPE have put our doctors, nurses, and caregivers in grave danger. An ongoing study by Kaiser Health News and *The Guardian* has identified at least 851 deaths among front-line health-care workers likely due to COVID-19.

From sea to shining sea, Americans are desperately hoping there are safe and successful vaccines on the market in the coming months. They need to be distributed in a fair, methodical, and medically sound way. Unfortunately, the country's experience over the past 5 months raises serious concerns about whether or not Americans can have any confidence this will be the case.

July 28, 2020

The Honorable Chuck Grassley
Chairman

The Honorable Ron Wyden
Ranking Member

U.S. Senate
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Senators Wyden and Grassley,

As Administrator of Hill Hospital, located in rural Sumter County, one of Alabama's poorest counties, I am proud of our response to COVID-19 despite the unprecedented challenges we faced due to the limited amount of personal protection equipment (PPE) at the onset of the COVID-19 pandemic.

I recall when Sumter County got its first case in March, our staff began to panic. Our doctors, nurses, and office staff questioned, "What are we going to do?" "How can our patients be protected? How can we be protected?" With very little PPE in-house, our small 27-bed and 4-emergency room facility began preparing for the worse.

We had a mere three weeks of PPE, so we immediately reached out to increase our stock; but we quickly ran into difficulty when we learned that our primary suppliers, Cardinal Health and Medline, had everything on back order. As our stock began to dwindle, our maintenance director of 40 years remembered that the hospital had a stockpile of PPE resulting from previous emergency preparedness efforts. That discovery would be our saving grace through March and April.

However grateful for this discovery, we again experienced a decline in PPE in May and June due to an increase in emergency room patients. Within two months, we had more than 300 patients presenting to the ER with COVID-19 symptoms, confirming 15 of them to be positive. By then, we were managing our PPE by keeping a small par level in each department, utilizing a sign-in sign-out system, and requiring nurses to reuse N95 masks for up to 5 days when they were not soiled or torn.

Doctors and nurses expressed their concerns as many have comorbidities and are over 60. They were afraid of putting their lives at-risk. To ensure safety, we began screening patients outside in a tent, which helped prevent an influx of patients and required minimum use of PPE.

The high demand for PPE has caused small rural hospitals like ours to question the integrity of our suppliers. While supplies from the State distribution center and other businesses have allowed for our continued day-to-day operation, the scarcity of resources from our usual suppliers is worrisome. Orders that were placed with these vendors in March still have not been filled. As a result, I am having to store PPE in my office to prevent exhaustion of our current supply.

PPE continues to be a serious concern for Hill Hospital. Without continuous access to these critical items, safety for both patients and our front-line providers is greatly jeopardized. Currently there are 354 confirmed cases with 15 deaths in Sumter County, according to the Alabama Department of Public Health. We are fearful of not being able to adequately service our community due to lack of PPE as COVID-19 continues to spread and the cold and flu season approaches.

Funding from the CARES Act has helped address some of our PPE shortage, allowing us to purchase supplies, although at much higher prices, from suppliers outside our normal purchasing group and to purchase at levels above our historical volume. Additionally, we have utilized this funding to create a safer environment for patient care by converting multiple isolation rooms with negative pressure.

Every day when I enter the halls of Hill Hospital, I am met with the faces of employees who are depending on me to ensure we maintain during and after COVID-19. I want to deliver; however, I need the appropriate resources to do so.

To this end, I am recommending that Congress consider the following:

- Guarantee that small rural hospitals have access to affordable PPE through private vendors, regardless of the volume of our orders;
- Continue to ensure that the State of Alabama receives the resources needed to help with the supply of PPE to the rural hospitals in our state; and
- Continue to fund rural hospitals post COVID-19 to prevent closure.

Over the past 6 years, Hill Hospital has had to make drastic changes to remain financially viable. Among other measures, we have decreased the hours and salaries of our staff and eliminated non-essential services. Just as we were experiencing a turn-around, a beacon of light, COVID-19 happened. I am fearful, that our small hospital will not be able to withstand the unprecedented financial pressure placed on us by COVID-19 without assistance from the federal government.

Again, I am very proud of the professionalism and commitment of the doctors, nurses, and staff of Hill Hospital, and I remain dedicated to ensuring the safety of these employees who put their health on the line every day to ensure that the residents of Sumter County receive the high level of care that they deserve.

Sincerely,

Loretta Webb Wilson, MBA/HCA
Administrator
Hill Hospital of Sumter County

From: Irene Agostini
To: Gartrell, Peter (Finance)
Cc: Michael E Richards; Kate Becker; Chamiza Pacheco de Alas; Nathan David Bush; Jessica Kelly; Barbara I Damron; Misty P Salaz
Subject: UNM PPE—from Irene Agostini MD
Date: Tuesday, July 28, 2020 5:22:06 PM

Peter,

This is my story. I have approval from our government relations officers and senior leaders to share this. Please reach out if you have any questions or concerns.

PPE experience at University of New Mexico Hospitals

I have been in health care for more than 30 years and have never even given a minute of my time to PPE until this year. As a physician and now

a Chief Medical officer at the only level one trauma center, the only safety net hospital and the only academic medical center in New Mexico, I deal with a myriad of issues. In my wildest nightmare, I would never have thought that I and many senior leaders would spend hundreds, if not thousands, of hours worrying about PPE.

In early February we began planning; by mid-March we were in full disaster mode at the University of NM Hospital. We realized that despite years of creating stores of PPE, we would quickly run out of PPE (especially N95s) if we did not create a conservation strategy. We formed a PPE committee consisting of senior physician leaders, nursing leaders, logistics, infectious disease experts, front line nursing staff and other staff. We still meet 5 days a week and have produced over a hundred guidelines about proper PPE usage and conservation methods. We began recycling PPE masks using aerosolized hydrogen peroxide. Our logistics team vetted hundreds of vendors—only one in ten was found to be reliable. Many asked for cash up front.

Our front-line staff needed enormous emotional support to care for a new disease that we all knew very little about. This was much more difficult with the need to conserve PPE in a way that was unthinkable in the US until this pandemic. Our ICU nurses had one N95 for a 12 hour shift—we knew that was safe but certainly not preferred. Our doctors stored their N95s in Tupperware so they could reuse them for up to 3 days since they were not in patients' rooms as much as the nurses. Our students were removed from the clinical setting because we needed to conserve the PPE for our staff. Due to the enormous efforts of our logistics team, with the support of NM's governor and our New Mexico Congressional Delegation, we were able to continue to procure PPE. We never had to suffer the nightmare of running out of PPE because of the enormous time and energy spent to conserve, as well as procure PPE. We have worked tirelessly to create trust amongst staff by meeting with all essential workers from our physicians to our environmental staff. We had hundreds of meetings, some with Spanish translators, so all of our staff could hear about our efforts to keep them safe despite the PPE shortage.

The emotional toll on our front-line health-care workers has been tremendous and the added fear of conserving PPE, so as not to run out, is egregious and seemingly unthinkable in the most expensive health-care system in the world.

Irene Agostini M.D.
UNM Hospitals
Chief Medical Officer
Assistant—Deb Gallegos
Email—dggallegos@salud.unm.edu

From: Krause, Erica (Brown)
To: PPEshortages
Subject: Toledo Ohio PPE Shortages
Date: Thursday, August 6, 2020 3:48:11 PM

Good Afternoon,

Below is an account of issues with PPE from Zepf Center in Toledo Ohio. They gave me permission to share their issues. Zepf is one of the largest mental health and addition services providers in Northwest Ohio.

Thanks,

Erica

Erica Krause
Northwest Ohio Regional Representative
Office of U.S. Senator Sherrod Brown
Erica—krause@brown.senate.gov

Date Wed, 5 Aug 2020 16:26:01 +0000
From Stephanie Kinsman <skinsman1@zepfcenter.org>
To "erica_krause@brown.senate.gov" <erica_krause@brown.senate.gov>

Cc Peter Areddy <pareddy@zepfcenter.org>, Adam Nutt <anutt@zepfcenter.org>, Andrea Powell <apowell@zepfcenter.org>
Subject RE: Request from Senator Brown's Office

Good Afternoon Erica,
 I am reaching out in response to Caryn's email below. As a Behavioral Health non-profit, we are seeing major disruptions in the normal supply chain. Below are some of the issues we have encountered.

1. Items on back order for months and then canceled right before they are supposed to finally be in stock, tying up needed funds for PPE that could have been allocated elsewhere.
2. Items commandeered at Customs for several weeks, even over a month in some instances.
3. Price increases on standard cleaning supplies that are in stock.
4. Zero availability on cleaning items from our standard vendors, requiring us to utilize resources online from companies we are not familiar with, putting us at risk for buying sub-par items.
5. An overwhelming amount of "KN95" masks available for purchase turn out to be counterfeit upon further research. We are having to go through rigorous hoops to ensure the products we receive are legitimate KN95s and the sites we purchase from are legitimate companies.
6. N95 masks are still very difficult to find at a reasonable price.

Additionally, because demand exceeds supply, costs of essential products will be unsustainable for nonprofits like Zepf without any additional assistance.

Sincerely,

Stephanie Kinsman
 Financial Operations Analyst
 Zepf Center
 2005 Ashland Ave.
 Toledo, Ohio 43620
 skinsman1@zepfcenter.org
 419-841-7701 ext. 6045

Erica Krause
Northwest Ohio Regional Representative
Office of U.S. Senator Sherrod Brown
 Erica_krause@brown.senate.gov

From: Sarah Delgado
To: PPEshortages
Subject: Responding to the call for information about PPE Shortages
Date: Friday, August 28, 2020 9:03:48 AM

To the Senate Finance Committee,

Thank you for putting out this call for frontline health-care workers to share their experiences with deficits of personal protective equipment (PPE). As the largest specialty nursing organization, representing the interests of the more than 500,000 acute and critical care nurses, we have followed this issue closely. Of note, because of ubiquitous and ongoing implementation of contingency strategies, we are now seeing normalized deviance in the use of PPE. Our members view extended use and reuse of equipment intended for single use as a normal practice. For instance, we have members say they have access to PPE, and in further discussion, note that they use the same single use N95 mask for a week or longer. This, along with recent research demonstrating the effectiveness of properly used PPE in protecting health-care workers from SARS-CoV-2 infection, makes current and future deficits an urgent problem.

Attached is our most recent letter to Congressional leaders describing priorities that must be included in Coronavirus Relief legislation. In addition, I've attached a list with summaries of 5 recent research studies published in peer-reviewed journals that demonstrate the mitigating impact of PPE on SARS-CoV-2 infection rates among health-care professionals. Thank you for your continued efforts to address ac-

cess to PPE for front-line health-care workers and specifically, your support of acute and critical care nurses.

--

Sarah A. Delgado, MSN RN ACNP
Clinical Practice Specialist, Strategic Advocacy
American Association of Critical-Care Nurses
P: 949-448-7347

From: Kim Zimmerman
To: PPEshortages
Subject: PPE
Date: Thursday, August 13, 2020 12:25:58 PM

I'm sharing this story from one of AHCA's members.

Thank you,
Kim Zimmerman
American Health Care Association
202-294-8981

Dear Senator Wyden:

Village Health Care is 106-bed independently owned nursing facility in Gresham, Oregon. The community was hit with an outbreak around March 20 with 16 staff cases and 20 cases in their resident population. My facility was well-prepared with a large stockpile of personal protective equipment (PPE) available onsite. However, given the burn rate associated with taking care of vulnerable populations during a pandemic, we ran through that stockpile within the first 10 days of their outbreak. We also had long-term, established relationships with several suppliers and had never experienced a supply chain disruption previously. After placing orders for more PPE, the suppliers would later inform us that they could not be filled.

From then on, we tried every option available to keep PPE on-hand and keep the residents and staff safe including:

- Immediately began following federal and state guidelines on how to conserve and ration PPE, in order to keep some supply on hand;
- Worked with state and local partners, but ultimately there was no consistent supply to be found;
- Received deliveries from the National Guard that were helpful but not even close to adequate in the long term; and
- Tried a variety of unconventional routes to find PPE, including working with an individual in our IT department who had established business relationships in China to source PPE directly.

While the supply chain has recovered somewhat from the early days of the crisis, Village Health Care, like many communities across the country, is still unable to rely on traditional suppliers or know if adequate supplies of all PPE items will continue to be available. PPE costs have also skyrocketed, just as care providers are requiring unprecedented amounts of PPE to deal with the COVID-19 pandemic. Village Health Care has been COVID-19 free since May 31st but still faces supply challenges in our efforts to keep COVID-19 out of their community.

Prior to COVID-19, a case of 100 gowns would cost \$75. After the crisis began, we now pay \$495 for the same 100 gowns—a 560% increase. The burn rate of PPE is extraordinary. Due to the 14 day-quarantine period necessary for new admissions and acuity of some of those residents, the community uses 400 gowns per day serving just 8 residents in a new admissions wing. That's nearly \$2000 in gowns alone daily, and that's only one small part of the community. We still care for others with non-COVID-19 infectious diseases—so there is a constant burn of PPE there as well.

As an independent community, Village Health Care has very few staff not engaged in direct caregiving and is unable to rely on a corporate office to manage supply chains.

We would appreciate any help Congress can provide to help on the PPE supply issues. With massively increased costs across the board, we relied on a PPP loan

as a critical lifeline, as well some funds from the Provider Relief Fund. Federal support will be crucial for the duration of this crisis.

Sincerely,

Gregory Madson, Administrator
 gmadson@villagehc.com
 Village Health Care
 3955 SE 182nd Ave.
 Gresham, OR 97030
 Main: 503-665-0183
 Direct: 503-676-3005
<https://villagehc.com/>

From: Jarone Lee
To: PPEshortages
Subject: PPE Story
Date: Friday, August 21, 2020 9:04:24 AM

Dear Senate Finance Committee:

I am a practicing emergency medicine and critical care physician on the frontlines of COVID-19 in one of our hot spot areas in the United States. I have cared for and continue to care for many COVID-19 patients. As such, I have witnessed the full range of devastating stories related to our patients and their families. Not all stories were sad. Many patients made remarkable recoveries despite prolonged critical-illness. However, none of the survivors would have made it without our front-line nurses, respiratory therapists, janitorial staff and physicians and their required PPE. My colleagues and I regularly talk about the burden of not only patient care, but also worrying about adequate PPE—will there be enough PPE tomorrow? Many bought their own PPE, some self-made. Others continue to need to use old and repurposed N95s. A lot of us wonder if the chemical smell from repurposing PPE is worse than COVID-19 itself.

All of this would not be an issue if we had adequate PPE so that we can safely and adequately do our jobs and treat our patients. We will continue to show up as front-line workers, not because we are heroes, but because we must and no one else can. We can only do so until we get sick. Please remember that us front-line health-care workers are highly trained and specialized for what we do. As more and more of us get sick from lack of PPE, there will be less and less of us to take care of America.

Jarone Lee, MD
 Emergency Medicine/Critical Care Physician

From: Williams, Christa (Christa)
To: PPEshortages
Subject: PPE shortages
Date: Monday, August 17, 2020 5:00:21 PM

I am a family physician faculty at a large public teaching hospital. We are still in a place of recycling our N95 masks. As you likely know, these masks were not meant to be re-used, especially not repeatedly. When our institution did receive a shipment of N95 masks from FEMA—they were too old to be safely used and all had to be discarded. This was infuriating, because we all know that whoever packaged those 20,000+ masks up for shipping, knew they were expired. We have 1 PAPR for our entire labor floor (50 beds, probably 300 staff+) which is necessary for anyone with facial hair or who fails fit testing. We have managed to be OK w/ gowns. We wipe down and reuse our masks. Our pharmacy manufactured hand sanitizer, which was incredibly helpful. But Oxyvir shortage is an ongoing issue—we have to use spray and paper towels.

It is so frustrating that months into this situation, front-line workers are reusing N95s.

Thank you,

Christa Williams, MD

From: Kristina Haley
To: PPEshortages
Subject: PPE Shortages
Date: Monday, August 3, 2020 1:09:44 PM

Good morning,

I am writing regarding PPE shortages. My name is Kristina Haley, and I am a pediatric hematologist/oncologist in Portland, OR. I take care of children with bleeding and clotting disorders, deficiency or dysfunction of various blood cells like red cells and platelets, children with cancer, and children who are undergoing or who have undergone bone marrow transplants. These are some of the most vulnerable patients in our children's hospital. During normal cold and flu season, we have strict guidelines regarding our interactions with these patients—we are required to sign in to each clinical space in order to declare ourselves fever and symptom free and we utilize the required protective equipment—changing gowns, gloves, and masks for every patient interaction. For my entire career, it has been explicitly told to me that I must change my PPE between every single patient. This provides them with the most protection. I have watched patients in our unit require ICU admission, require mechanical ventilation, and die from viruses that typically cause regular cold symptoms in otherwise healthy individuals.

In addition to caring for some of our most vulnerable patients, I too am on an immune modulating agent for a myeloproliferative neoplasm. I am unsure if my medication or my disease put me at higher risk for infection or at higher risk for severe infection. But, I have to assume they do. I live in a state that has not seen the extraordinary strain on resources that other states have seen. I am not trying to utilize garbage bags as isolation gowns as I have heard other health-care workers have had to utilize. I am being told to re-use my face mask as long as possible—to keep using it between patients in order to minimize the number of masks I ultimately use. This goes against everything I have been told prior to the COVID-19 pandemic regarding optimal utilization of PPE. In addition, my patients are in home-made masks that do not fit correctly and are not made of adequate materials. The Oregon Health Authority recommended that patients wear surgical masks but we do not have the supplies for this. I fear I am putting my patients and myself at risk. I go into each patient encounter with anxiety for myself and for them.

I am not a hero. I am a well-trained and well-educated resource. I want to take the best care of my patients, but I also must continue to protect myself so that I can continue to take the best care of my patients going forward. Sending healthcare workers as well as other people who interact with the public on a daily basis without adequate protection is not heroism. It is irresponsible. It is unethical. It is dangerous.

Please get us the supplies we need to do the jobs we are trained to do. Stop calling us heroes—it doesn't make us feel better. Call us well-equipped professionals who can manage crises and get us the PPE we need to do the jobs we are well-trained to do.

Thank you,

Kristina
 Kristina Haley, DO
 Associate Professor
 Oregon Health and Science University

From: Petee, Barb
To: PPEshortages
Subject: PPE Shortages/a story from frontlines/ProMedica
Date: Monday, August 31, 2020 5:18:24

The following is sent on behalf of Nicole Justus, MSN, RN, Hospital Incident Management Team/Logistics Section Chief, ProMedica

ProMedica is a health system based in Toledo, Ohio. Please do not hesitate to let me know if you need additional information or have any questions.

To the Senators of the Finance Committee:

I am a nurse. Though I am not working directly with patients at this time, I do serve nurses and other healthcare workers who work directly with patients. I would like to tell you the story from my own “front line.” When the COVID-19 pandemic struck, my organization, ProMedica, quickly followed the Hospital Incident Command System (HICS) and assembled a team. I was asked to coordinate the Logistics section of the HICS, and our Supply Chain division immediately began trying to source, purchase and distribute PPE. We knew the need for it would be greater than anything we had experienced before.

From the start, we encountered obstacles. Our normal suppliers were unable to meet the new, increased demand, not just from us, but from their customers nationwide. We put the word out to our community—businesses, organizations and individuals responded generously, donating everything they had: a paint shop sent us all the masks they had on hand, a local nursing school sent us their isolation gowns, hair salons and tattoo parlors sent us their last boxes of gloves. And although this generosity rescued us in the beginning, we knew it wouldn’t—couldn’t—last and we would need to get creative.

We investigated every non-traditional supplier of PPE we could think of (for instance, food and beverage industry suppliers). We worked with local engineers to use 3D printers to make some of our equipment. And ultimately, with CDC guidelines in place while assuring patient and staff safety, we had to change the way we practiced. As I’m sure you are aware, almost all PPE is typically only used once and then discarded. This includes gowns, gloves, masks, and respirators. But in this crisis, we needed to consider *re-using* our PPE. We asked ourselves: how can we protect our staff AND still take care of patients? We were determined to not have to choose between the two. Fortunately, we never had to make that decision, but it felt like we came close. Thanks to devoted infection preventionists, we established protocols that would allow for the safe re-use of our PPE. It wasn’t optimal, it wasn’t what we would have chosen if we had alternatives, but it’s what we had to do in this unprecedented situation. We knew, though, that these unavoidable changes in practice were not ideal and ran counter to our employees’ years of experience. Our leaders care deeply about the safety of patients and staff, and I witnessed members of our leadership team in tears because we had to make the difficult decision to reuse and reprocess supplies.

Let me discuss one piece of personal protective equipment in particular—the N95 respirator. An N95 respirator is pivotal in the prevention of the spread of COVID-19. Of all the PPE we attempted to source, this one proved, and continues to prove, the most difficult. We went to extraordinary lengths to obtain PPE: we paid higher than list price; we chartered a plane to pick up PPE out of state; we entered into collaborative agreements to increase our purchasing power. But also, we ordered, and paid for, a shipment of N95s that never made it to our organization; we ordered, and paid for, a shipment of N95s that turned out to be counterfeit. We were so hopeful that we could finally relieve some of the burden of reprocessing, but it was not to be. Despite the fact that reprocessing has been given an EUA by the FDA, and that we’re all doing it, and it seems to have relieved some of the pressure, make no mistake—this is not an ideal situation for our staff or our patients. Until we return to normal, we are stressing an already precarious situation.

We continue to experience difficulties. Special gowns for staff who provide chemotherapy are unable to be ordered. We recently nearly exhausted our supply of medium gloves, the size worn by most of our staff. We moved to an industrial (instead of medical) supplier of gloves to fill in the gaps while we waited for our regular suppliers to continue shipments. And we are still reprocessing N95s. Our staff are still using them more than once. If adequate amounts of N95s exist from suppliers that aren’t going to price-gouge us into bankruptcy, they are not making it to the hospitals that need them. We are not confident that the supply chain will remain stable and be able to fulfill our needs if we resume “traditional” use of PPE. We fear every day that we may run out.

Our staff are the real heroes—working under these conditions is stressful and scary. We will continue to do everything we can, everything we must, but we could really use your help. Any boost to the PPE supply chain, especially N95s, would be appreciated more than you could know.

Respectfully submitted,

Nicole Justus, MSN, RN
ProMedica
Hospital Incident Management Team—Logistics Section Chief

Please direct questions or inquiries to:

Barbara J. Petee
Chief Advocacy and Government Relations Officer
ProMedica
MSC-S39000
100 Madison Avenue
Toledo, Ohio 43604
419-260-2800
(Cell) 567-585-3894
barb.petee@promedica.org

From: Allison Edwards
To: PPEshortages
Subject: Lack of PPE
Date: Thursday, August 20, 2020 3:17:23 PM

Senator Wyden:

I run a small primary care clinic in Kansas City, Kansas.

We have had—and continue to have—difficulty in purchasing PPE. We've had to get creative with gloves, masks, gowns and have been sourcing our hand sanitizer from local shops (since medical suppliers are out).

We're largely re-using PPE that under normal circumstances we'd use once and toss.

I think the hardest part is not knowing when/if 1) the Pandemic will end and 2) when the PPE shortage will end.

So in the mean time, we're doing the best we can with what we've got.

(And on a bright note, we were able to contribute to a bulk buy facilitated by *weneedppe.org* and were able to get 100 gowns for the practice so that we could continue to provide COVID testing!)

Happy to elaborate more, but I fear my story is the same as almost anyone else's who is trying to run a small clinic.

Allison Edwards, MD
allison.m.edwards@gmail.com
Founder and Medical Director
Kansas City Direct Primary Care
@KansasCityDPC
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www.kansascitydirectprimarycare.com

From: Yuet Mui Kong
To: Rodriguez, Isabel (Hirono)
Cc: PPEshortages; Luna, Nicholas (Hirono)
Subject: Hawaii's PPE Shortages—Share Your Experience with Senator Hirono
Date: Monday, August 31, 2020 10:41:01 PM

Aloha Senator Hirono,

I would like to share my experience. Hawaii's PPE shortages have started in February, 2020. My workplace's suppliers/vendors have not been able to provide us stable supplies. Most of the time, items are on back order. Hence, I signed up as many as PPE donation websites and PPE purchase groups as possible—official and unofficial (via social media), nationally and internationally.

Since then, many vendors have approached me. However, they either take bulk order only, *e.g.*, minimum order of 10,000 masks each time, or cannot provide proof of quality. I have been spending a lot of time to verify the “certificates” they send me, and counter check with the NIOSH list and FDA/CDC list. In addition, I also need to keep up with the news in case the manufacturers drop out of the lists or lose government contracts, *e.g.*, following the news about BYD in California.

Being on the official lists does not mean the masks are not counterfeit. If I am lucky to get some samples, I will need to check if the quality meets standards, if the design is the same as the photos on the manufacturer’s official website, and if the address printed on the box is the same as address listed on their website, etc. Fortunately, I am able to read Chinese to verify the information. When masks are made in the other countries, I need to contact my friends and relatives in those countries to verify the information. It is very time consuming. Needless to say, the price for surgical/procedural masks has increased from \$15/box of 50 to over \$55 per box of 50!

In my experience, a lot of surgical/procedural masks I tested cannot protect our frontline staff from COVID-19. Some masks are not even waterproof which means they cannot block any droplets. Some masks’ filter layer is almost see-through. The staff would be at risk if they used those masks.

When I thought I found a reliable, genuine N95 source to replace the most popular brand’s N95s, the Federal contracted sterilization facility only sterilizes the “common” N95 masks that meet its criteria. Which means I need to start the process over again to find my co-workers another affordable masks with reliable quality and meet its sterilization requirements. In addition, most of the medical staff in Hawaii only passes the fit testing with N95 size small. Most of our staff cannot pass the test if they use size regular or universal. So, it is almost like mission impossible.

We don’t know how much longer we need to face the shortage and at the same time, to keep ourselves safe to continue to serve our patients and community.

Thank you for your kind attention.

Aloha,

Yuet “Mui” Kong
Chief Operations Officer
Kokua Kalihi Valley Comprehensive Family Services
2229 N. School Street
Honolulu, HI 96819
Tel: 808-791-9413
Fax: 808-848-0979

From: Krause, Erica (Brown)
To: PPEshortages
Subject: Elara Caring—Home Health NW OH/MI
Date: Friday, August 7, 2020 9:10:46 AM

Good Morning,

Below is an email I received from Elara Home Health regarding their issues obtaining necessary PPE. They have faced significant challenges because prior to COVID they did not routinely need medical grade N95 masks. Trying to enter that market during the pandemic has proved nearly impossible. Ms. Brewer would be happy to talk further with the committee.

Thanks,

Erica

Email from Rebecca Brewer, RN—Area VP Midwest-East Michigan/Ohio—Elara Caring

“We have been unable to secure N95 masks from medical supply companies due to allocations. This is not an item as a skilled home care provider we used often prior to March. Never more than a dozen or so a year, if that. Because of this there is no allowable allocations for us to order them from supply companies. Companies like 3M are, from what I understand, directed to provide these to hospitals and maybe government supplies stocks instead of providers like Elara? I am not well versed on the situation producers are in other than being told we are not able to get them

directly from the factory. We are especially in need of small size N95 masks. Dave Cook our VP of Procurement recently told me on his last call to 3M he was informed that 3M is on a 4 billion mask backlog right now and not making small sizes. The standard sizes often do not provide a proper fit on our primarily female work force. 95% of what we have secured and used since March are N95 masks that were donated by construction companies that are primarily larger males. This has left us in the situation of only having a small number of staff that were able to pass a fit test to see patients. In many of these cases the staff member is still using the same single mask they were fitted into 4 months ago. This is very concerning as we head in to what looks to be a very stressful winter for front line workers. Hospitals are leaning on companies like Elara Caring to keep patients home where the risk of nosocomial infection is marginal and saving inpatient space for COVID-19 patients. Without additional supplies this is going to become extremely difficult. Some of the other very basic items that continue to be available in limited supply (if at all) due to allocations: Fit testing kits for protective N95 and above masks (I have still not been able to secure a kit since March—luckily we had a few of these on hand); Fit testing solution; Alcohol Swabs; Thermometers; Basic wound care/dressing supplies; Gloves—all sizes and materials; Gowns; Procedure/surgical masks of all types; Surgical caps; Shoe covers; Catheters, drainage bags and insertion supplies. I would be happy to get on a call and discuss our experiences further or participate anyway that would be helpful. I have been a nurse for 23 years and have never experienced anything close to what the last few months have brought to the table. Thank you for advocating for our staff. Thank you for reaching out to us for input!”

Best,

Rebecca Brewer, RN | Area Vice President Midwest—East
Michigan/Ohio
c 517-581-8896 | f 800-379-1600 | rbrewer@elara.com

Erica Krause
Northwest Ohio Regional Representative
Office of U.S. Senator Sherrod Brown
Erica—krause@brown.senate.gov

COMMUNICATIONS

CENTER FOR FISCAL EQUITY
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Statement of Michael G. Bindner

Chairman Grassley and the Ranking Member Wyden, thank you for the opportunity to submit these comments for the record. Excerpts were also sent to the Ways and Means Trade Subcommittee from last week. The next three paragraphs, however, are new to this hearing.

I also omitted my comments about Hyperstagflation. I see from the Senate version of the draft bill that our views and those of the majority are the same, although \$100 is a bit too low. May I suggest \$350, which is a good halfway point and leaves worker with \$800 a week total. Rent will get paid and food will be bought.

The irony is that I tested positive for PAN-SARS yesterday, although I had the severe version of the virus. We shall see if this is a false positive or, worse, it can be extreme twice. May I suggest a panel of COVID patients to relate their experiences. This is also relevant because it goes to the quality of testing. If the false positive rate for tests is too high, we may have less documented cases than we know, at the same time that we have a much greater number of real cases, like mine, where medical attention was not sought because there were no serious SARS symptoms. Many have had only the cold, the latent contagious stage and the non-contagious fatigue stage where we manufacture immunity (which my blood test yesterday did not detect).

More to the point, many manufacturing workers, including those in the medical supply system, have likely tested positive but may not have actually been sick, while others are never tested but are among the walking wounded—although, as I say below—no one can work with extreme fatigue symptoms, which is a concern as to the welfare of undocumented workers who likely don't have the luxury of sick leave benefits. This worker illness and the related shutdown will impact medical suppliers in the United States in areas where the virus is active, which means the entire South and West, with the Midwest being the next on deck. Repeated material follows.

This testimony relies on my experience as a member of the Cost Management Systems project of what was then called Computer-Aided Manufacturing—International, now the Consortium for Advanced Management—International. The project produced *Cost Management for Today's Advanced Manufacturing*. I created a handbook based on the project, the *U.S. Air Force Orientation Guide to Advanced Cost Management*.

One of the topics addressed is the manufacturing environment known as Process Simplification, which features Just in Time supply chains. This model works for Walmart, which is massively integrated, and for defense production. Parts arrive with little holding time and go right out the door. If everyone is working in the supply chain, it works beautifully. Commercially, it is essentially a rationalized production line from resource extraction to delivery.

As long as the line is not stopped, it minimizes waste and non-value-added cost. It doubles down on traditional manufacturing's stance of labor being a cog in the machine. Unionization is not compatible with it unless they have incentives to keep things moving (like in the defense sector, which requires cleared and more specialized workers).

Recent reported experience on Midwest food production has workers being made to work sick, or after exposure. The CDC model has been flawed, but they have finally added a runny nose to the list of symptoms (as I predicted they must, having had the virus myself). The virus has not been contained, not through lack of correct distancing but because the economy was closed in areas where it had not arrived, which meant reopening just as it has gone from early exposure to full-on illness. Because nasal symptoms were discounted, people likely transmitted in private settings, with transmitters not knowing their sneezes were potentially deadly and not hay fever.

Testing positive for exposure means someone sneezed. Not knowing that this is the trigger means workers were idled (or not idled) at the wrong time. There is no danger that workers with SARS or fatigue symptoms will keep working. It is impossible to do so. If they do not have sick leave, the results could be tragic. Undocumented workers have even more dire consequences in their personal supply chain, which includes remittances and cramped living conditions that ensure virus transmission. The attached table shows how states will be affected under current policy.

At this stage of the pandemic, the assembly line is about to crash. A new round of mandated closings is inevitable unless mandate quarantine to the period from the first sniffle to three weeks after they stop for everyone in the household. Unless there is significant cross training already in place, the supply of goods will begin to diminish.

There is simply no stock of inventory to rely on in this model. Farmers will again be overwhelmed with unsold food that they will not able to move. It will be worse in this round unless courageous action is taken on personal quarantine and in the CDC's understanding and guidance of how the virus spreads and does not spread. I doubt that the medical hierarchy has it in them.

Please see the attached table, which predicts that there will be at least 400,000 US deaths if national mortality rates are even 80% of those in New York.

Thank you for the opportunity to address the committee. We are, of course, available for direct testimony or to answer questions by members and staff.

State	Population (millions)	Projected deaths @0.12%
Alabama	4.9	5,880
Alaska	0.73	876
Arizona	7.28	8,736
Arkansas	3.02	3,624
California	39.51	47,412
Colorado	5.76	6,912
Connecticut	3.57	4,284
Delaware	0.97	1,164
District of Columbia	0.71	852
Florida	21.48	25,776
Georgia	10.62	12,744
Hawaii	1.42	1,704
Idaho	1.79	2,148
Illinois	12.67	15,204
Indiana	6.73	8,076
Iowa	3.16	3,792

State	Population (millions)	Projected deaths @0.12%
Kansas	2.91	3,492
Kentucky	4.47	5,364
Louisiana	4.65	5,580
Maine	1.34	1,608
Maryland	6.05	7,260
Massachusetts	6.89	8,268
Michigan	9.99	11,988
Minnesota	5.64	6,768
Mississippi	2.98	3,576
Missouri	6.14	7,368
Montana	1.07	1,284
Nebraska	1.93	2,316
Nevada	3.08	3,696
New Hampshire	1.36	1,632
New Jersey	8.88	10,656
New Mexico	2.1	2,520
New York	19.45	23,340
North Carolina	10.49	12,588
North Dakota	0.76	912
Ohio	11.69	14,028
Oklahoma	3.96	4,752
Oregon	4.22	5,064
Pennsylvania	12.8	15,360
Rhode Island	1.06	1,272
South Carolina	5.15	6,180
South Dakota	0.88	1,056
Tennessee	6.83	8,196
Texas	29	34,800
Utah	3.21	3,852
Vermont	0.62	744
Virginia	8.54	10,248
Washington	7.61	9,132
West Virginia	1.79	2,148

State	Population (millions)	Projected deaths @0.12%
Wisconsin	5.82	6,984
Wyoming	0.58	696
		393,912

HEALTHCARE LEADERSHIP COUNCIL

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Washington, DC 20001
202-452-8700

July 30, 2020

The Honorable Chuck Grassley, Chairman
The Honorable Ron Wyden, Ranking Member
U.S. Senate Committee on Finance
219 Dirksen Senate Building
Washington, DC 20510

Dear Chairman Grassley and Ranking Member Wyden:

The Healthcare Leadership Council (HLC) commends the Senate Committee on Finance for holding its hearing on, “Part 2: Protecting the Reliability of the U.S. Medical Supply Chain During the COVID-19 Pandemic.” We applaud the promptness with which you and your colleagues in the U.S. Senate and House of Representatives have addressed policies and priorities related to disaster preparedness under these extraordinary circumstances.

The HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation’s healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC—hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, home care providers, and information technology companies—advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach. We are uniquely positioned to address disaster preparedness comprehensively from all perspectives in the healthcare industry.

HLC members are pleased to announce that we are working with the Duke-Margolis Center for Health Policy on an initiative aimed at strengthening the public-private partnership that is essential to disaster preparedness and response. As part of this initiative, as we are also working with the Deloitte consulting firm to bring its expertise to our endeavor.

Like you, we believe there is much to be learned from the collective response thus far to the COVID-19 pandemic. In the summer and fall of 2020, we will be bringing together the expertise of the Duke-Margolis Center, the multisector perspectives of the HLC membership, and ideas from key individuals and organizations—from the public sector as well as the Administration and Congress—involved in the current pandemic response to assemble a set of innovative, integrated solutions that will, one, determine what is working well in the current COVID-19 response and needs to be maintained and even strengthened and, two, what aspects of our disaster preparedness and response require fresh thinking and new approaches.

Our work will be concentrated in three primary areas:

- **Supply chain readiness.** Particularly in the early stages of the COVID-19 pandemic, we witnessed difficulties and disruptions in the distribution of critical goods and supplies including personal protective equipment and testing supplies. It is essential that we call upon the expertise of the private sector to build a disaster-ready supply chain that can work with government at all levels to ensure that our nation’s needs are met and that future treatments and vaccines can be delivered safely and expeditiously.
- **Care delivery.** We have learned a great deal during the current pandemic about how to expand healthcare reach to meet extraordinary escalations in pa-

tient demands. It is essential to translate those lessons into a systemic approach that incorporates components such as telehealth, workforce mobility, adequacy and resiliency, and financial stability for healthcare providers during periods when normal revenue streams are disrupted.

- **Data and evidence generation.** Our ability to respond to a nationwide health crisis relies heavily on the ability to access and analyze data rapidly and effectively. This must involve well-coordinated public-private cooperation to gather data and utilize it to improve patient care, strengthen public health surveillance, and accelerate biomedical innovation while protecting the privacy of individuals.

Through this initiative, contributions from the nation's premier experts in both healthcare and disaster preparedness will be coalesced into a set of specific recommendations and commitments that will strengthen our nation's preparedness and response for future health crises. We will be sharing ideas with your committee as this initiative progresses.

Legislative Priorities

In addition to the broad-based policy initiative mentioned above, HLC members also urge your committee and others in Congress to address a set of legislative actions that will help reduce barriers to disaster preparedness and response. These legislative priorities are outlined below.

Workforce

- Implement a federal waiver of state licensure and allow for practice at the top of the scope of license for physicians, nurses, pharmacists, pharmacy technicians and other healthcare professionals in times of disaster. This should also allow nurses to work in centralized locations to provide services, including remote patient monitoring across state lines.
- Allow license portability for non-physician providers for Medical Disability Exam vendors with the Veterans Administration (VA) in parity with what is allowed for providers who work within the VA health systems. Specifically, license portability is needed for Medical Disability Exam vendors for providers such as nurse practitioners, physician assistants, audiologists, psychologists, and more.
- Enable swift allowance of temporary visas for nurses, physicians, pharmacists, and healthcare professionals (especially those who have already completed clearances) to address need in times of disaster.
- Continue to encourage states to temporarily waive in-state nurse licensing and scope of practice requirements for the duration of the COVID-19 pandemic, allowing nurses to work in a centralized location to provide services, including remote patient monitoring across state lines.
- Direct the Department of Homeland Security to take the following actions to increase the supply of physicians during the national emergency:
 - Temporarily suspend the enforcement of the 2 year home residency requirement for any J-1 medical resident or fellow who is willing to work full time in a Health Professional Shortage Area (HPSA) or Medically Underserved Areas and Populations (MUA/Ps) or in a medical field that is directly treating COVID patients or assisting in the battle against COVID. This should not be restricted to just the Conrad 30 Waiver program. There are many other Interested Government Agency (IGA) Waivers including Appalachian Regional Commission (ARC), Delta Regional Authority (DRA) VA Waivers, and Health and Human Services (HHS) Waivers.
 - Temporarily make exempt from the annual H-1B cap any physician, or healthcare worker (as long as they are H-1B classifiable positions) involved in direct patient care who may be called upon to join the fight against COVID-19.
 - Temporarily extend the status and work authorization of any H-1B physician beyond the normal 6-year limit for the duration of the COVID-19 crisis or at least 1 year.
 - Require U.S. Citizenship and Immigration Services to reinstate premium processing for any H-1B filed for a physician, physician assistant, registered nurse, nurse practitioner, and any other critical healthcare professional for the purpose of fighting COVID-19.
 - Temporarily suspend the VisaScreen Certificate or equivalent requirement for healthcare professionals.

- Temporarily grant current J-1 medical residents and fellows the ability to engage in COVID patient care even if that is not a part of their formal training program.
- Permanently expand waivers to permit pharmacists to diagnose and prescribe testing and treatment for COVID-19 and related influenza-like illnesses (in accordance with FDA approvals and treatment guidelines) in times of an emergency declaration. Additionally, recognize pharmacists as Medicare providers so that they may be reimbursed for these services.

Healthcare Coverage and Costs

- Provide federal premium subsidies for group continuation coverage (COBRA and state continuation that goes beyond COBRA) of at least 90 percent, preferably 100 percent, to people who lose health coverage because of COVID-19.
- Support temporary federal risk mitigation programs to support the financial stability of insurers and self-insured employers during the duration of COVID-19.
- Waive cost sharing for COVID-19, and COVID-19 mutations, testing, vaccine administration and treatment.
- Expand the payroll tax credit provided under the Coronavirus Aid Relief and Economic Security (CARES) Act for providing group health coverage for tax years 2020 and 2021, from 50 percent up to 100 percent of payroll taxes. Or, Congress should establish a direct grant program to fund employers that wish to continue their group health coverage during the pandemic.
- Establish a special enrollment period, allowing uninsured Americans to purchase coverage on the exchanges.
- Enhance the individual market tax credits (APTC) to reduce premiums for individuals, for individuals between 400 percent and 600 percent of the federal poverty level, because premium costs for those individuals often far exceeds 10 percent of income.
- Implement continuous eligibility for current Medicaid beneficiaries during the public health emergency.
- Provide additional FMAP, in line with National Association of Medicaid Directors' requested percentage, for states to address Medicaid program growth and high-acuity beneficiaries.
- Require CMS to compare MA plans 2020 Star Ratings and 2021 Star Ratings and use the higher scores to hold plans harmless due to data collection challenges during the crisis. In addition, CMS should provide plans having a 3.5 or 3 Star Ratings with the opportunity to earn a Quality Bonus Payment (QBP) for contract years 2022 and 2023 (2021 and 2022 Star Ratings) of at least 3.5 percent to improve program stability and the stability of benefit offerings for beneficiaries' given the COVID-19 public health emergency.
- While CMS recently provided additional guidance enabling Medicare Advantage organizations to submit diagnosis for risk adjustment payment from telehealth visits, plans need certainty that this policy will continue to be implemented moving forward. Therefore, Congress should codify that starting in 2020, CMS must adjust MA plan enrollee's risk scores to consider diagnosis data obtained through telehealth services covered by the plan.
- Bolster mental/behavioral health and social determinants of health support to address the COVID-19 ramifications.

Provider Support

- The CARES Act that included over \$100 billion for providers is a welcome step, but it has proved insufficient for many providers. Congress must further support healthcare providers who are losing revenue during the COVID-19 pandemic and help them ramp back up efficiently when the system is ready to return to more normal business. While aid based on historic Medicare fee-for-service (FFS) payments may be the easiest and quickest way to provide support, as noted by CMS, it fails to meet all needs, including:
 - Providers who have moved to value-based care, such as Medicare Advantage and other Medicare-sponsored value-based programs;
 - Providers with a large Medicaid or other non-Medicare FFS population;
 - Providers with a significant number of COVID-19 patients; and
 - Providers located in rural areas serving a predominantly rural population.
- Help expand the public health infrastructure to support better bi-directional electronic information exchange between public health disease registries, labs, and electronic health records.
- Allow healthcare providers a 0% interest rate as part of the Accelerated and Advanced Payments provision under the CARES Act.

- Allow a temporary increase in Medicare and Medicaid disproportionate share (DSH) allotments during public health emergencies.
- Enable hospitals, health systems and other providers to be compensated for costs associated with remote patient monitoring, which otherwise meets evidence-based guidelines and appropriate patient data security and privacy standards, through direct federal funds that explicitly includes Registered Nurse-supported COVID-19 remote patient screening and monitoring solutions, creation of new reimbursement mechanisms, or a waiver of existing billing requirements.
- Provide additional financial support for in-home personal care attendants/caregivers.
- Provide support for mobile phlebotomy to eliminate delays in cancer diagnostic testing and mitigate risks associated with clinic and hospital visits for immunocompromised patients.
- Provide liability protections for healthcare providers should they be placed in a position of making resource allocation and treatment decision trade-offs.
- Provide immediate relief to teaching hospitals by temporarily doubling Indirect Medical Education (IME) payments.
- Extend by two years the Graduate Medical Education (GME) cap building period for new teaching hospitals that are currently within the five-year period that determines GME reimbursement caps.
- Impose a two-year moratorium on finalizing the Medicaid Fiscal Accountability Regulation (MFAR), as states and healthcare providers will not be able to implement the proposal during or in the aftermath of the pandemic or absorb the financial impact.
- Provide leniency and/or immunity under Occupational Safety and Health Administration (OSHA) rules for issues related to PPE shortages unless gross negligence can be proven.
- Provide essential support to the fitness center industry to ensure the continuation of employee and senior wellness programs. These programs provide invaluable services to millions of Americans during times of economic insecurity and uncertainty. Maintaining wellness program access for seniors will promote health and well-being, preventing an escalation in long-term healthcare costs. There are multiple options for providing this support: inclusion of the fitness center industry in the SBA PPP program, providing business interruption insurance, offering lease relief, or creating a 9/11-style recovery fund.

Regulatory Relief

- Expand on CMS' allowance for Medicare Part B drugs to be administered in a home setting, in times of an emergency declaration if the patient and the patient's physician believe it is critical to help protect the patient's safety and health, by allowing the home administration supplier to be able to directly bill CMS for the items and services provided. However, we acknowledge that this additional flexibility may not be appropriate for oncology drugs unless HHS, working with the oncology community, deems it safe and appropriate.
- For those interventions that otherwise meet evidence-based guidelines and appropriate patient data security and privacy standards, waive strict application of remote patient monitoring coding requirements, such as the minimum time standards, which may limit providers' ability to use them and pose an undue documentation burden during the public health crisis.
- Grant a one-year extension of the implementation date of the CMS and ONC Interoperability and Information Blocking Final Rules to January 1, 2022 since the healthcare sector as a whole does not have time, personnel or funding to implement the rules during the pandemic.
- Amend Section 1135(b) of the Social Security Act by giving the Secretary authority to adjust benefits and administrative procedures for Medicare Advantage plans to match changes made in Medicare FFS.
- Amend Section 1135(b) of the Social Security Act to clarify the authority to waive certain HIPAA requirements for the duration of a public health emergency, rather than only for 72 hours.
- Enact the National Telehealth Strategy and Data Advancement Act (H.R. 5763) to ensure coordination of telehealth activities.
- Allow expansion of tools that can be used to determine disability (VASR-D) and that can be used as part of a mobile examination, particularly serving veterans in remote or medically underserved areas or in homeless communities, during this time of national emergency.
- Allow for partial completion of the Document-Based Questions (DBQs) when determining disability ratings through the Veterans Administration. DBQs that

are only partially completed but meet the requirements of the VASR-D for rating of the claimed disability should be deemed sufficient for rating purposes and should not adversely affect the quality ratings of either the VA personnel utilizing the DBQs or the vendor completing and delivering the DBQ.

Innovation

- Enact the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act (H.R. 4100) to encourage innovation of new antibiotics to fight antimicrobial resistant (AMR) infections by providing additional reimbursement to hospitals that need to use these high-need antibiotics. These antibiotics incur significant cost to develop and while they are often the most appropriate therapy to treat AMR infections, the structure of the DRG mechanism creates a financial disincentive for their use. These drugs need to be made readily available and appropriately reimbursed for hospitals especially during the COVID-19 pandemic.
- Create public incentives to ensure private investment in improved vaccine technologies to address this and future pandemics.

As the committee moves forward on issues related to disaster preparedness, we stand ready to be a trusted resource that encompasses the perspective of all stakeholders in the private sector committed to working in collaboration to be better prepared should another pandemic occur. Thank you for your efforts to gather information to ensure our country remains vigilant. HLC looks forward to continuing to collaborate with you on our shared priorities. Should you have any questions, please do not hesitate to contact Debbie Witchey at dwitchey@hlc.org or Tina Olson Grande at tgrande@hlc.org

Sincerely,

Mary R. Grealy
President

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July 30, 2020

The Honorable Charles Grassley
Chairman
U.S. Senate
Committee on Finance
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
U.S. Senate
Committee on Finance
Washington, DC 20510

Dear Chairman Grassley and Ranking Member Wyden:

On behalf of the National Association of Manufacturers, I write to thank you for holding today's hearing, "Part 2: Protecting the Reliability of the U.S. Medical Supply Chain During the COVID-19 Pandemic." The NAM is the nation's largest industrial trade association, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturers are concerned about the rise in fake and counterfeit products, which cost the U.S. economy nearly \$131 billion and more than 325,000 jobs in 2019 alone.

The COVID-19 pandemic has brought new urgency to the fight against counterfeits. Fake goods not only reduce U.S. jobs and infringe on creators' intellectual property rights, but also threaten consumer health and safety. Counterfeit test kits and unsafe PPE peddled to unwitting consumers can exacerbate the public health crisis that our nation faces.

Manufacturers have developed several policy proposals to combat counterfeits, which are detailed in the attached report. In brief, we urge policymakers to (1) require e-commerce platforms to reduce the availability of counterfeits; (2) modernize

enforcement laws and tactics to keep pace with counterfeiting technology; (3) streamline government coordination to tackle counterfeit items; and (4) empower consumers to avoid counterfeit goods. In addition, we recognize that any lasting solution will require stronger collaboration among all private sector stakeholders.

On behalf of the millions of men and women who make things in America, thank you for your attention to this important issue.

Sincerely,

Chris Netram
Vice President, Tax and Domestic Economic Policy

Countering Counterfeits: The Real Threat of Fake Products

How Fake Products Harm Manufacturers, Consumers, and Public Health— and How to Solve This Problem

Amid an unprecedented global health crisis, manufacturers have stepped up and taken the lead, working together and with national, state and local governments to fight the spread of COVID-19. Manufacturers deliver day-to-day necessities, life-saving medical innovations and products that improve people's lives in countless ways. While the pandemic has demonstrated anew the importance of American innovation and ingenuity, it has also revealed a serious threat: counterfeit products that put lives and livelihoods at risk.

Counterfeiting is not a new problem; it has harmed manufacturers, American workers and consumers for years. But the problem is getting worse, and the COVID-19 pandemic has shown just how dangerous inaction can be. As part of the nation's critical response effort, manufacturers have been supplying health-care workers and other Americans on the front lines of this crisis with vital goods, including personal protective equipment, hospital beds, ventilators, hand sanitizers, cleaning supplies and other critical health-care and safety products. But while manufacturing men and women work long hours to ramp up production of desperately needed products to fight the spread of this deadly illness, counterfeiters have exploited the crisis to peddle fake tests, dangerous vaccines and ineffective protective gear. These counterfeits are harming American citizens and hindering manufacturers' efforts to protect their workers and communities.

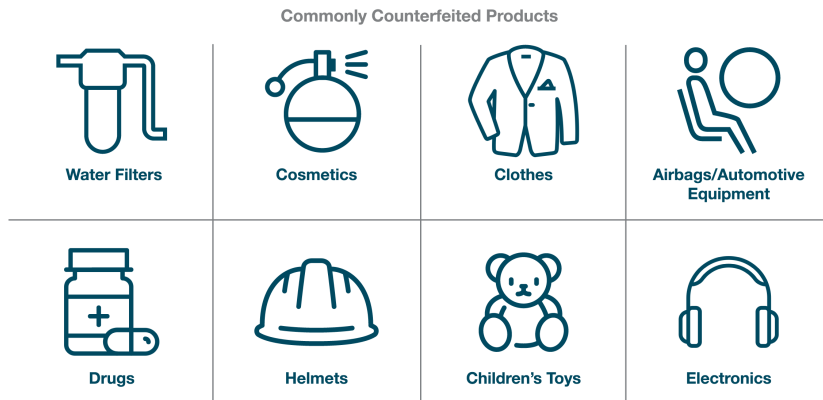
The prevalence of counterfeits in the COVID-19 response has brought new urgency to this long-simmering issue. So the National Association of Manufacturers is leading the charge against fake and counterfeit goods, bringing together diverse stakeholders and driving innovative policy solutions to address these issues once and for all and to ensure the long-term success of our sector and the safety and security of the people who rely on our products.

Jay Timmons
President and CEO
National Association of Manufacturers

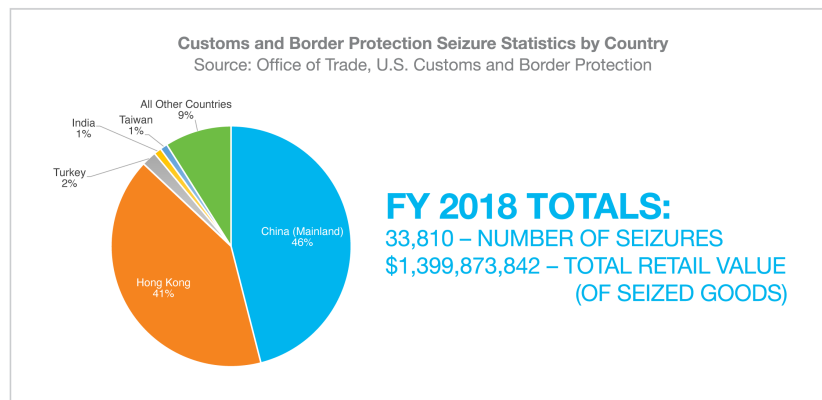
I. Counterfeits and the Threat to Manufacturers

Counterfeit goods are a threat to manufacturers and to the consumers they serve. Fake products have infiltrated everyday avenues of commerce, making their way into supply chains and consumers' homes. The problem is not limited to specific sectors: it affects a broad range of manufactured goods, from automotive parts and children's toys to medical devices and pharmaceuticals. The rise of counterfeits threatens manufacturers' competitiveness, undermines consumer confidence and poses a threat to individuals' health and safety.

By one estimate, global trade in counterfeit and pirated goods exceeded \$500 billion in 2016, which amounts to 3.3% of all global trade.¹ Even this number likely fails to capture the full scope of the problem. Attempts to understand the scale of counterfeit goods are tied to the data on counterfeit goods seized by officials at Customs and Border Protection. It is estimated that authorities in the United States catch less than 2.3% of the total volume of counterfeit goods.²



China is the top global hub for counterfeiting. In 2019, more than 8 of every 10 counterfeit products seized at U.S. borders came from China or Hong Kong, dwarfing the volume of counterfeits from any other country or region.³ Chinese counterfeits challenge U.S. manufacturers not only in China and in the United States, but also in markets across Asia, Africa and the Americas. Tackling these problems requires working more closely with trading partners to enhance enforcement, capacity building and joint advocacy.



¹ Trade in fake goods is now 3.3% of world trade and rising, ORGANIZATION FOR COOPERATION AND DEVELOPMENT (March 18, 2019), <https://www.oecd.org/newsroom/trade-in-fake-goods-is-now-33-of-world-trade-and-rising.htm>.

² COMMISSION ON THE THEFT OF AMERICAN INTELLECTUAL PROPERTY, THE THEFT OF AMERICAN INTELLECTUAL PROPERTY: REASSESSMENTS OF THE CHALLENGE AND UNITED STATES POLICY, UPDATE TO THE IP COMMISSION REPORT 9 (2017), http://ipcommission.org/report/IP_Commission_Report_Update_2017.pdf.

³ U.S. CUSTOMS AND BORDER PROTECTION OFFICE OF TRADE, INTELLECTUAL PROPERTY RIGHTS SEIZURE STATISTICS: FY 2019 14 (2020), https://www.cbp.gov/sites/default/files/assets/documents/2020-May/FY%202019%20IPR%20Seizure%20Powerpoint%20FINAL%20PBRB%20APPROVED_0.pdf.

E-Commerce: Captive to Counterfeits?

Counterfeiters have gained strength due to the growth of e-commerce platforms, which have transformed how companies connect with customers and changed the marketplace for selling goods. E-commerce sales now make up 10% of all retail spending, up from 3% of total sales in 2009.⁴ Pre-COVID-19 estimates predicted that global e-commerce sales would exceed \$4 trillion in 2020,⁵ with U.S. e-commerce spending to exceed \$1 trillion by 2025, doubling the volume from 2018.⁶ The spike in e-commerce during the COVID-19 pandemic has only pushed these numbers higher.⁷

While these platforms have created opportunities for manufacturers to sell their products and provided new conveniences for consumers, they have also created a pipeline directly to customers that bad actors can exploit. Millions of third-party sellers can easily access these platforms without providing basic information about their identity or location, and the platforms themselves exert little oversight over these sellers. Counterfeiters are therefore better able to pose as legitimate sellers to profit off of fake goods. Because bad actors are often able to hide their identities, it is difficult for the government and the private sector to hold them accountable even after they are discovered.

A surge in counterfeits accompanies a growth in e-commerce. E-commerce sales have grown and are expected to exceed \$4 trillion by 2020.⁸

Online platforms present unique challenges for manufacturers who must devote ever-increasing resources and time to monitoring search engine results, e-commerce channels, social media postings, payment providers and others who may all play a role in driving online traffic to counterfeit products.

Bosch like other manufacturers faces the dilemma in effectively dealing with counterfeiters present in online marketplaces. There are several key challenges to dealing with online counterfeits. Counterfeiters are able to market goods that appear to be legitimate, often using the brand owner's own online content, making it difficult to identify counterfeits without a purchase. The sheer volume of listings can also pose a challenge to enforcement. Finally, the counterfeiters are able to effectively hide the true person or entity hidden behind the digital curtain separating them from the consumers in the online marketplaces. Even though some online marketplaces have tools to report sellers, the brand owner is unable to take measurable actions against the infringing seller without more knowledge of the seller's identity. In the current environment, the brand owner's ability to thoroughly defend its intellectual property is hampered.

– *Clayton Lindgren, Senior Manager, Country Approval and Brand Protection, Robert Bosch LLC*

During the COVID-19 pandemic, counterfeiters—who have long preyed on vulnerable consumers to make a profit—have taken advantage of consumers' increased anxiety and fear, the high demand for certain goods and the substantial increase in e-commerce necessitated by social distancing measures.⁹ COVID-19 has required manufacturers to adapt to new demands and innovate new products at record speeds, further complicating the challenges of fighting counterfeits.

⁴Joe Kaziukenas, *U.S. E-Commerce Posts Fastest Growth in Seven Years*, MARKETPLACE PULSE (November 20, 2019), <https://www.marketplacepulse.com/articles/us-e-commerce-posts-fastest-growth-in-seven-years>.

⁵U.S. GOVERNMENT ACCOUNTABILITY OFFICE, GAO-18-216, INTELLECTUAL PROPERTY: AGENCIES CAN IMPROVE EFFORTS TO ADDRESS RISKS POSED BY CHANGING COUNTERFEIT MARKET 12 (2018), <https://www.gao.gov/assets/690/689713.pdf> [hereinafter GAO-18-216].

⁶Kaziukenas, *supra* note 4.

⁷April Berthene, *Shoppers Buy More Online Compared To Before the Pandemic*, DIGITAL COMMERCE 360 (June 8, 2020), <https://www.digitalcommerce360.com/article/coronavirus-impact-online-retail/>.

⁸GAO-18-216, *supra* note 5, at 12.

⁹*See, e.g., Jay Kennedy, Buyer Beware: Counterfeit markets can flourish during a public health crisis*, THE CONVERSATION (March 26, 2020), <https://theconversation.com/buyer-beware-counterfeit-markets-can-flourish-during-a-public-health-crisis-134492>; Europol, *How Criminals Profit From the Covid-19 Pandemic* (March 27, 2020), <https://www.europol.europa.eu/newsroom/news/how-criminals-profit-covid-19-pandemic>; Daniel Bennett, *Covid-19 and Counterfeiting: How the Pandemic Is Reshaping Brand Protection—Part 1* (April 2, 2020), <https://www.corsarch.com/covid-19-counterfeiting-how-pandemic-reshaping-brand-protection/>.

Peddling Fakes During a Pandemic:

Counterfeit products have seriously complicated COVID–19 response efforts, with increasing reports of untested test kits, counterfeit pharmaceuticals and fake respirator masks. As legitimate manufacturers worked to develop and manufacture critical COVID–19 tests and test supplies, unscrupulous actors used the uncertainty to sell dangerous knockoffs. In April 2020, the Department of Homeland Security announced it “worked alongside U.S. Customs and Border Protection to seize over 225 shipments of mislabeled, fraudulent, unauthorized or prohibited COVID–19 test kits, treatment kits, homeopathic remedies, purported anti-viral products and personal protective equipment (PPE).”¹⁰ As CBP seized thousands of test kits entering the United States through International Mail Facilities, the U.S. Food and Drug Administration warned consumers about the fraudulent tests being sold online.¹¹ Amazon announced that it blocked or removed more than 1 million products that contained suspect claims about COVID–19 treatments and applications.¹²

Counterfeiters operating as third-party sellers on popular e-commerce platforms can undercut legitimate manufacturers’ sales because they are not subject to the same rules and standards. They can sell products for a fraction of the price because they have not invested in the research and development to create new products. The products they are shipping have not gone through the same safety tests or been built to the same stringent standards as products made by the manufacturers who follow the rules.

E-commerce platforms unfortunately benefit from counterfeit products as well, making a profit from third-party sales of counterfeits just as they do from legitimate sales. Amazon made \$53.76 billion in revenue from third-party sales in 2019, up from \$42.75 billion in 2018.¹³

Without a level playing field, manufacturers face challenges competing and maintaining their technological edge. Without products subject to testing and standards, consumers face real threats to their health and safety.

Impact on Manufacturers: The Cost of Counterfeits

Counterfeits threaten manufacturers’ investments in innovation and violate manufacturers’ intellectual property rights. Manufacturers in the United States perform nearly two-thirds of all private-sector research and development, totaling \$271 billion in 2018.¹⁴ Safeguarding manufacturers’ intellectual property rights is critical to manufacturers’ continued ability to grow and innovate. Counterfeiting can slow economic growth and lead to job loss in IP-intensive industries.¹⁵

The Economic Costs:

With counterfeits making up 3.3% of total merchandise trade, the U.S. economic impacts are staggering. For 2019, counterfeiting would have subtracted nearly \$131 billion from the U.S. economy, including direct, indirect and induced economic impacts. That means \$22.3 billion of lost labor income, 325,542 fewer jobs, \$5.6 billion of lost federal tax revenues and nearly \$4 trillion less in state and local tax collections.¹⁶

In addition to misappropriating manufacturers’ valuable IP, counterfeiters undermine the brand names and business reputations that manufacturers invested money

¹⁰ICE HSI Launches Operation Stolen Promise, U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT (April 15, 2020), <https://www.ice.gov/news/releases/ice-hsi-launches-operation-stolen-promise>.

¹¹1,147 Prohibited Test Kits Seized by Chicago CBP in 45 Days, U.S. Customs and Border Protection (May 1, 2020), <https://www.cbp.gov/newsroom/local-media-release/1147-prohibited-test-kits-seized-chicago-cbp-45-days>; Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments, U.S. Food and Drug Administration (April 29, 2020), <https://www.fda.gov/consumers/consumer-updates/beware-fraudulent-coronavirus-tests-vaccines-and-treatments>.

¹²See, e.g., Catherine Thorbecke, Amazon removes 1 million products for misleading claims, price gouging amid coronavirus outbreak (March 3, 2020), <https://abcnews.go.com/Business/amazon-cracks-million-misleading-price-gouged-products-amid/story?id=69357582>.

¹³J. Clement, Third-party seller share of Amazon platform 2007–2020, STATISTA (May 4, 2020), <https://www.statista.com/statistics/259782/third-party-seller-share-of-amazon-platform/>.

¹⁴National Associating of Manufacturers, Facts About Manufacturing: Top 18 Facts You Need to Know, <https://www.nam.org/facts-about-manufacturing/> (last visited June 16, 2020).

¹⁵CONGRESSIONAL RESEARCH SERVICE, RL34292, INTELLECTUAL PROPERTY RIGHTS AND INTERNATIONAL TRADE (May 12, 2020), <https://fas.org/sgp/crs/row/RL34292.pdf>.

¹⁶Data from NAM Chief Economist Chad Moutray running global counterfeit totals through IMPLAN (on file with author).

and time to establish. Counterfeiters infringe on trademarks and confuse consumers as to the quality and origin of products and services. They undermine the confidence and quality that trademark laws are intended to support.¹⁷

Counterfeits force manufacturers to divert resources away from critical business operations and focus on policing platforms and protecting their brands. Companies spend huge sums to employ global networks of investigators, retain brand-protection experts and pursue enforcement against counterfeiters.¹⁸ Each dollar spent to fight counterfeits is a dollar not spent to improve products, develop new technologies, grow employee wages or create new American jobs.

Small and medium-sized manufacturers are likely to be harmed the most by the counterfeit market. These companies have fewer resources to invest in the personnel and technology to monitor illicit activity and protect their brands. Government enforcement efforts often rely on information provided by brand owners, and smaller manufacturers are less able to engage with government entities responsible for enforcing their IP rights. Smaller firms are also more at risk to be driven out of business by counterfeiters. They often offer fewer products than their larger counterparts, which means that harm from counterfeits cannot be easily offset. Smaller firms are less able to absorb the losses that come when counterfeiters siphon off their business.

Impact on Consumers: The Dangers of Counterfeits

Consumers come in direct contact with some of the most common types of counterfeit products, including cosmetics, toys and pharmaceuticals. Many can pose real dangers to their health and safety. According to CBP, 16% of the 31,560 shipments of counterfeit goods they seized in 2016 contained products posing threats to consumer health and safety.¹⁹

The threats to individuals can be severe. Counterfeit products integrated into electronics such as chargers and hoverboards have caused fires and physical harm. Faulty components that make their way into critical auto safety products like airbags can undermine these lifesaving mechanisms. Items like helmets falsely claiming to meet government-approved safety standards have failed to perform their functions and resulted in deaths.²⁰

The COVID-19 pandemic has made the threat to consumers even more obvious. The appearance of fake testing kits, unsafe pharmaceuticals and counterfeit masks has caused confusion among anxious consumers and exacerbated public health risks in the current crisis.²¹ As families are staying home more often, they are going online to purchase toys to keep children entertained, desks and chairs to set up home offices, outdoor power equipment to tend to their homes and recreational equipment to stay in shape. Manufacturers of all these products have reported high levels of counterfeits that create serious, even fatal, risks to consumers.

As the current COVID-19 pandemic has unfortunately illustrated, health-care products will continue to be one of the most commonly targeted industries for counterfeiters. We are likely to continue to see illicit medical devices, drugs and personal care products entering legitimate supply chains. This is a problem that impacts patients and consumers in the U.S. and across the globe. At Johnson & Johnson, we invest significant resources to aggressively pursue this illegal activity but we believe businesses must join together and partner with governments to become a greater force in fighting the growing threat of counterfeits. Our ultimate goal always is to keep patients and consumers safe but we cannot do it alone.

– **Rich Kaeser, Vice President of Global Brand Protection, Johnson & Johnson**

¹⁷J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION, §2:5 (4th ed. 2015).

¹⁸GAO-18-216, *supra* note 5, at 18-19.

¹⁹*Id.* at 2.

²⁰Alexandra Berzon, et al., *Amazon Has Ceded Control of Its Site. The Result: Thousands of Banned, Unsafe or Mislabeled*, *The Wall Street Journal* (August 23, 2019), https://www.wsj.com/articles/amazon-has-ceded-control-of-its-site-the-result-thousands-of-banned-unsafe-or-mislabeled-products-11566564990?mod=article_inline.

²¹See, e.g., Jay Kennedy, *Buyer Beware: Counterfeit markets can flourish during a public health crisis*, *THE CONVERSATION* (March 26, 2020); *How Criminals Profit From the Covid-19 Pandemic*, *EUROPOL* (March 27, 2020).

The Need for Action Now

The threats to manufacturers and consumers underscore the need for swift action against counterfeits. There is no silver bullet for tackling the diverse set of factors that have allowed counterfeits to proliferate. But the COVID-19 environment demonstrates the need for action and presents a new opportunity for the government to tackle this long-standing problem.

Counterfeiting is a complex problem that requires unwavering commitment from the private and public sectors to solve. UL's Project Centurion, an effort to reduce counterfeit products in the marketplace by leveraging a global safety network, led to over 270,000 counterfeit UL Marked products seized globally in 2019, valued at \$23 million. UL's Anti-Counterfeiting Innovation Center combines expertise from law enforcement, retailers, e-commerce platforms, government officials and others to address complex counterfeiting challenges, reframe problems and implement innovative solutions. The Center aims to lead in anti-counterfeiting innovations that drive globally relevant, cost-effective solutions that advance public safety and build capacity within law enforcement and private sector organizations to combat IP crime.

– *Brian H. Monks, Vice President and Chief Security Officer, UL*

II. Policy Solutions and Call to Action

REQUIRE E-COMMERCE PLATFORMS TO REDUCE THE AVAILABILITY OF COUNTERFEITS

THE CHALLENGE

To reduce the harm caused by counterfeits, stakeholders must work to eliminate the availability of counterfeit goods for purchase. Fewer counterfeits on the market mean fewer consumers harmed by fake goods and fewer financial incentives for counterfeiters to operate. The challenge today is identifying and advancing policies and programs that policymakers, retailers, e-commerce platforms and brand owners can collectively adopt to limit the availability of as many counterfeit goods as possible.

Several key market factors drive counterfeiting, including the ability of counterfeiters to turn a profit, their access to global markets and a lack of accountability for bad actors.²² The most important of these, however, is profit. Indeed, the higher potential profitability of counterfeiting itself—based on their ability to free-ride with respect to research, development and marketing costs while accessing cheaper production processes and materials—creates the incentive for entities to engage in counterfeiting over legitimate production.²³ By using e-commerce platforms and selling directly to consumers, counterfeiters can cut out the middleman and further increase their profit margins.²⁴

The Internet and e-commerce platforms have provided counterfeiters with access to global markets through easily accessible sales and distribution channels. A factory in China can quickly create an online account with a platform and begin selling directly to consumers around the world. These same channels also allow counterfeiters to avoid liability for the harm caused by counterfeit goods and continue to pursue their illicit operation. Counterfeiters can use false identities and addresses and then vanish at the first sign of trouble.²⁵

E-commerce platforms have democratized retail sales and enabled small, often remote, legitimate manufacturers to compete in the global marketplace. Tackling the

²² Although limited, research shows that counterfeiting and piracy are driven by both demand- and supply-side factors embedded in institutional, behavioral and cultural environments. However, for purposes of limiting the *availability* of counterfeits, this paper focuses on the supply-side only. See Seung-Hee Lee and Boonghee Yoo, *A Review of the Determinants of Counterfeiting and Piracy and the Proposition for Future Research*, 24 KOREAN JOURNAL OF POLICY STUDIES 1, 6 (2009), <https://pdfs.semanticscholar.org/ad71/3f727bc224ab79ffc8b999bdede50b0e8a26.pdf>.

²³ See *id.* at 19.

²⁴ See Jon Emont, *Amazon's Heavy Recruitment of Chinese Sellers Puts Consumers at Risk*, THE WALL STREET JOURNAL (November 11, 2019), https://www.wsj.com/articles/amazons-heavy-recruitment-of-chinese-sellers-puts-consumers-at-risk-11573489075?mod=cx_picks&cx_nav_source=cx_picks&cx_tag=collabctx&cx_artPos=1#cxrecs_s.

²⁵ See, e.g., *id.* at 21 (citing ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, *The Economic Impact of Counterfeiting—Counterfeiting and Piracy Overall Assessment* (2006)); Daniel Chow, *Alibaba, Amazon, and Counterfeiting in the Age of the Internet*, NORTHWESTERN JOURNAL OF INTERNATIONAL LAW AND BUSINESS, Forthcoming (August 22, 2019); Ohio State Pub. L. Working Paper No. 497 (2019), <https://ssrn.com/abstract=3441110>.

problem of counterfeiters on e-commerce platforms should be done in a way that does not undermine the value these platforms provide to legitimate manufacturers, many of whom operate as good-faith, third-party sellers on these online marketplaces. Solutions should be crafted to target the parts of the system that counterfeiters can exploit, and they should increase the cost for counterfeiters by ensuring accountability for bad actors.

THE SOLUTIONS

- Congress should enact legislation to require e-commerce platforms to strengthen upfront screening of potential vendors. Congress should require e-commerce platforms to take the following key steps or face contributory liability for infringement due to vendor activities on their platforms:
 - Collect and verify key information (such as representative identity, address and contact information and bank account information) prior to vendor listing.
 - Require potential vendors to attest, with appropriate proof, that the goods sold on the platform are authentic and authorized and have appropriate legal documentation required for sale in the United States where necessary.²⁶
 - Maintain a current, verified set of the information referenced above for each vendor (through ongoing audits and reverification) or face the risk of contributory liability in the event of counterfeiting enforcement.
 - Require a vendor to attest that it is only using images on its product listing sites that it is authorized to use and that accurately depict the goods being sold, and require it to conduct due diligence on submitted images to ensure that they appear to be accurate.
 - Conduct due diligence, including use of appropriate technology, to screen for counterfeit products prior to offering the seller's goods for sale.
 - Screen potential vendors and products prior to approval to ensure that previously terminated vendors, or previously delisted products, do not reappear on platforms under a different vendor or a different alias.
- Congress should enact legislation that requires e-commerce platforms to share information relevant for consumers to understand the risk of purchasing counterfeits and for brand owners to pursue effective enforcement actions against counterfeiters. Congress should require platforms to take the following key steps or face contributory liability for infringement due to vendor activities on their platforms:
 - Provide to the public the full name and contact information of the vendor.
 - Provide to the public information about whether the listed vendor is the manufacturer, importer, reseller and/or retailer of the product.
 - Notify the consumer prior to purchase of any given product if the vendor supplying a product is different from the vendor named on the product listing page.
- Congress should enact legislation that requires e-commerce platforms to remove promptly counterfeit vendors and products from their platforms. Congress should require e-commerce platforms to take the following key steps or face contributory liability for infringement due to vendor activities on their platforms:
 - Develop and use technology solutions to routinely screen for, and proactively remove, counterfeit products.
 - Implement a timely, accessible takedown process for removing listings of counterfeit goods.
 - Terminate sellers that have sold counterfeit goods on the platform.
- Congress should appropriate emergency funds to boost enforcement against fake and counterfeit versions of products urgently needed for COVID-19 treatment and care such as test kits, medicines, personal protective equipment and other health supplies:

²⁶Such information could include a chain of title or license (to demonstrate that their product sales are authorized), legal certifications such as a Children's Product Certificate (to meet requirements by U.S. safety certification bodies) or other demonstrations of conformity with appropriate U.S. standards.

- Those funds should be routed through the National Intellectual Property Rights Coordination Center to ensure interagency sharing of real-time intelligence and coordinated ramp-up of enforcement efforts. The FDA should play a key role in providing up-to-date information to both consumers and government agencies on products requiring FDA approval and the status of approvals to ensure appropriate border enforcement against counterfeit products.
- Congress should strengthen the ability of key government agencies to protect American consumers from fake medical products by ensuring the FDA has full and clear statutory authority to destroy counterfeit medical products.

MODERNIZE ENFORCEMENT LAWS AND TACTICS TO KEEP PACE WITH COUNTERFEITING TECHNOLOGY

THE CHALLENGE

Fighting counterfeits requires a legal framework and robust enforcement to hold bad actors accountable. This means the government, brand owners and e-commerce platforms must work together to enforce IP, trade and consumer protection laws, which collectively protect brands from unfair competition and consumers from harm.²⁷

Despite the resources expended by these stakeholders to fight them, counterfeits continue to enter the U.S. marketplace at an increasing rate.²⁸ This problem has only been exacerbated as criminals look to capitalize on the need for essential items to address the COVID-19 health crisis.²⁹ The ineffectiveness of enforcement efforts against counterfeits is not due to a lack of effort³⁰ but to multiple factors combining to give counterfeiters a decided advantage against enforcement efforts.

Current U.S. law fails to appropriately hold e-commerce platforms accountable for their role in the rise of counterfeits, despite the evidence that fake goods have proliferated on the Internet. By allowing counterfeiters unparalleled access to consumers worldwide and the ability to vanish into cyberspace at the first sign of trouble, e-commerce platforms offer counterfeiters the perfect avenue for selling fakes while avoiding liability.³¹ The immense revenue generated from third-party sales coupled with various gaps and safe harbors in U.S. laws have empowered e-commerce platforms to dispense with basic oversight responsibilities that would prevent counterfeits from being sold on them.

Gaps in current U.S. statutes and a lack of case law have enabled e-commerce platforms to avoid being held liable for contributory trademark liability, even where they fail to take sufficient actions to address counterfeits. Under the legal concept of contributory trademark liability, an entity may be held liable for selling counterfeits even though they do not actually engage in the

²⁷ Esther A. Zuccaro, *Gucci v. Alibaba: A Balanced Approach to Secondary Liability for E-Commerce Platforms*, 17 North Carolina Journal of Law and Technology On. 144, 159 (2016) (citing J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION, §2:2 (4th ed. 2015)).

²⁸ A recent report by the Organisation for Co-operation and Development and the European Union Intellectual Property Office, for example, shows that global trade in counterfeit and pirated goods has exploded in recent years, with the value of imported fake goods increasing from \$461 billion in 2013 (2.5% of world trade) to \$509 billion in 2016 (3.3% of all global trade). OECD, *supra* note 1.

²⁹ See, e.g., Jay Kennedy, *Buyer Beware: Counterfeit markets can flourish during a public health crisis*, THE CONVERSATION (March 26, 2020), <https://theconversation.com/buyer-beware-counterfeit-markets-can-flourish-during-a-public-health-crisis-134492>; Europol, *How Criminals Profit From the Covid-19 Pandemic* (March 27, 2020), <https://www.europol.europa.eu/newsroom/news/how-criminals-profit-covid-19-pandemic>.

³⁰ As noted by the coheads of Venable's Copyright and Trademark Litigation Practice, "While rights holders scour online marketplaces and investigate and report counterfeits to the marketplaces, and some marketplaces have stepped up proactive enforcement, the sheer volume of listings and ease with which sellers can enter the e-commerce market mean that counterfeiters have the advantage." Meaghan H. Kent and Nicholas W. Jordan, *Congress Acknowledges Dramatic Shift Toward E-commerce with Bipartisan Bills Aimed at Reducing Counterfeits*, VENABLE (May 8, 2020), <https://www.venable.com/insights/publications/2020/05/congress-acknowledges-dramatic-shift-toward>.

³¹ As the Third Circuit recently recognized, the inability for customers to contact third-party sellers directly "enables third-party vendors to conceal themselves from the customer, leaving customers injured by defective products with no direct recourse to the third-party vendor." *Oberdorf v. Amazon.com Inc.*, 930 F.3d 136, 145 (3d. Cir. 2019). See also GAO-18-216, *supra* note 5, at 2.

actual counterfeiting activity.³² This is a legal concept created through the courts³³ and lacks the clear standards necessary for courts to adequately apply it to new and emerging situations or technologies—such as what legal obligations e-commerce platforms should have in preventing the sales of counterfeits on their platforms.³⁴ Without a clear legal standard or legislation that would offer clarity in such cases, courts are left struggling to clearly define when an e-commerce platform may be held liable for its role in the sale of counterfeits.

Because e-commerce and its role in the proliferation of counterfeits are relatively new, whether and to what extent contributory trademark liability applies in this context is unclear. As such, courts often sidestep the issue or parties are likely to settle out of court.³⁵ In other cases where courts do attempt to address the issue, laws that were not intended to protect e-commerce platforms from selling dangerous products are interpreted as providing them a legal safe harbor.³⁶ Both Congress and the administration have explicitly highlighted the need to assess liability for e-commerce under both contributory trademark infringement and product liability law to combat counterfeits,³⁷ steps that manufacturers generally support.³⁸ Such clarity is especially important to ensure courts can hold e-commerce platforms accountable when they are willfully blind and allow fake products to be falsely advertised as genuine.³⁹

Our law enforcement bodies lack modern legal authorities, resources and tools that are effective against counterfeiters. Policymakers have failed to update enforcement tools to keep pace with the increasingly sophisticated technologies

³²Contributory trademark liability is a means by which an entity may be held liable for selling counterfeits even though they do not actually engage in infringing activities in certain instances, such as where “it knows or has reason to know” the product was fake. *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844, 847–850 (1982); see also 35 U.S.C. §271(c).

³³*Tiffany Inc. v. eBay, Inc.*, 600 F.3d 93, 103 (2d Cir. 2010) (“Contributory trademark infringement is a judicially created doctrine that derives from the common law of torts.”).

³⁴See Eric Goldman, *eBay Mostly Beats Tiffany in the Second Circuit, but False Advertising Claims Remanded*, TECHNOLOGY AND MARKETING LAW BLOG (April 1, 2010), <https://blog.ericgoldman.org/archives/2010/04/ebay-mostly-bea.htm> (“In a subtle opinion with potentially significant implications, eBay has preserved most of its big 2008 district court victory in the long-running *Tiffany v. eBay* case. However, as seems to be the norm with federal appellate opinions, the opinion intentionally sidesteps some key open doctrinal questions squarely raised by the case—such as if the Second Circuit recognizes the nominative use defense, or the Second Circuit’s standards for contributory trademark infringement. As a result, we don’t get the clean and decisive doctrinal standards that help make a case truly precedent-setting . . .”).

³⁵See Paul Mazur, *In Fight Against Fakes, Alibaba and Owner of Gucci Go From Adversaries to Partners*, THE NEW YORK TIMES (August 3, 2017), <https://www.nytimes.com/2017/08/03/business/alibaba-kering-fakes-luxury.html>.

³⁶One such statute is Section 230 of the Communications Decency Act, which as intended to shield online platforms for *communication* on their platform, but not the sale of dangerous harmful goods. However, while Section 230 should not be interpreted to protect the sale of harmful goods, manufacturers still support its application to protect online social platforms from the speech of third parties. See, e.g., 47 U.S.C. §230(c)(1); *Green v. American Online*, 318 F.3d 465,471 (3d Cir. 2003) (providing that Section 230 of the CDA “precludes courts from entertaining claims that would place a computer service provider in a publisher’s role, and therefore bars lawsuits seeking to hold a service provider liable for its exercise of a publisher’s traditional editorial functions—such as deciding whether to publish, withdraw, postpone, or alter content.”); Beatrice Martinet and Reinhard J. Oertli, *Liability of E-Commerce Platforms for Copyright and Trademark Infringement: A World Tour*, AMERICAN BAR ASSOCIATION (2015). See also *Oberdorf*, 930 F.3d at 152.

³⁷See U.S. DEPARTMENT OF HOMELAND SECURITY, COMBATING TRAFFICKING IN COUNTERFEIT AND PIRATED GOODS REPORT TO THE PRESIDENT OF THE UNITED STATES 33 (2020), https://www.dhs.gov/sites/default/files/publications/20_0124_ply_counterfeit-pirated-goods-report_01.pdf; see also Kent and Jordan, *supra* note 30 (noting recently introduced legislation that would “amend the Trademark Act of 1946 to provide for contributory liability for e-commerce platforms for use of a counterfeit mark by a third-party seller unless the platforms satisfy certain statutory requirements.”).

³⁸While manufacturers support the need for legislation to ensure that e-commerce platforms cannot evade liability for the sale of counterfeits over their platform by being willfully blind, such legislation must be careful not to prescribe overly rigid requirements that may prevent e-commerce platforms from developing and utilizing innovative solutions to prevent the sale of counterfeits and assist in locating counterfeiters.

³⁹See *Tiffany Inc.*, 600 F.3d at 109 (holding that, with regard to eBay’s potential contributory liability for “facilitating” third parties’ infringing sales, the relevant standard to assess eBay’s liability was the *Inwood* test, which only required the court to determine whether eBay continued to supply its services to sellers when it *knew or had reason to know* they were engaging in trademark infringement, rather than whether it could have prevented it. In doing so, the court enabled e-commerce platforms to continue to avoid liability by being willfully ignorant).

and practices used by counterfeiters.⁴⁰ The effective enforcement against counterfeiters is throttled due to gaps in current U.S. counterfeiting laws, which define “counterfeiting” too narrowly,⁴¹ fail to account for the likelihood the counterfeit product may contribute to or cause death or physical injury and fail to appropriately assign liability and award remedies based on counterfeiters’ potential harm.⁴² As a result, a glaring disparity exists between the moral culpability and actual harm caused by counterfeiters and the penalties and remedies that arise from it.⁴³

Under both U.S. civil and criminal law, for a court to find a product to be a “counterfeit” and impose the severe penalties such a designation carries with it, the product must be a clear copy of a registered trademark.⁴⁴ But products that are almost identical and contain trademarks that differ by only a couple of letters are merely “infringing marks,”⁴⁵ which carries no threat of jail time or even monetary penalties. This means that a defendant selling unverified, fake COVID-19 test kits, for example, would not be considered a “counterfeiter” and would face no risk to penalty under IP laws because no patent exists for such test kits yet. Similarly, a defendant found guilty of selling fake, but generically labeled, pharmaceuticals will face no risk of prison or fines despite the fake drugs imperiling human life,⁴⁶ while a defendant guilty of counterfeiting identical fake handbags “may be required to pay thousands, if not millions, of dollars in damages and/or fines, and may be sent to prison.”⁴⁷

Finally, brand owners are left to fight counterfeiters alone since consumers who ingest fake drugs or buy lead-ridden toys, for example, are afforded no special avenue for relief under federal law,⁴⁸ despite the fact that the consumer is often the primary victim of counterfeiting and, in some instances, suffers serious physical injury.⁴⁹

⁴⁰ See Christo Hall, *The need for sophisticated anti-counterfeit technology is ever-growing as the practices of counterfeiters become increasingly advanced*, PATHOGENS AND GLOBAL HEALTH (May 2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4001489/> (“Overt visible markers on a drug’s packaging have been commonly used to identify the genuine from the fake. but the holograms and distinguishing markers applied to the blister foil, film or paper substrates of the packaging are mimicked and imitated to a high level of accuracy. To the untrained eye, the genuine and fake examples can look identical.”).

⁴¹ Under both civil and criminal U.S. law, a “counterfeit” trademark is defined as a “spurious mark” that is “identical with, or substantially distinguishable from a registered mark,” and whose use is “likely to cause confusion.” 15 U.S.C. § 1127. In practice, courts are also often reluctant to label a product a counterfeit unless the infringing defendant’s is a clear copy of the registered trademark. See Sandra L. Rierson, *Pharmaceutical Counterfeiting and the Puzzle of Remedies*, 8 WAKE FOREST INTELLECTUAL PROPERTY LAW JOURNAL 433, 434 (2008) (citing *Colgate-Palmolive Co. v. J.M.D. All-Star Import and Export, Inc.*, 486 F. SUPP. 2d 286, 291 (S.D.N.Y. 2007)).

⁴² See Rierson, *Pharmaceutical Counterfeiting*, at 445–448, 454 (noting that neither the Lanham Act nor the 1984 Trademark Counterfeiting Act—the two main federal statutes that create civil and criminal liability for trademark infringement—“explicitly considers the nature of the defendant’s counterfeiting—e.g., the type of goods being passed off [or the risk of harm posed by such good]—in fashioning his punishment or the extent of his liability”).

⁴³ *Id.*

⁴⁴ While injunctive relief, rather than damages, is all that is available in the form of relief in trademark infringement cases, when a defendant crosses into counterfeiting, courts “shall” award treble damages, or at the plaintiff’s election, statutory damages of up to \$100,000 per mark and \$1 million per mark if it is willful. 15 U.S.C. § 1117. In addition to these civil remedies, the Federal Trademark Counterfeiting Act of 1984 established criminal penalties for anyone who “traffics in” counterfeit goods intentionally, imposing a \$2 million fine and up to 10 years in jail for deliberate trademark counterfeiting and authorizing fines of up to \$5 million for repeat offenders. 18 U.S.C. §§ 2318–2320.

⁴⁵ 15 U.S.C. § 1114(1)(a) (defining trademark infringement as the unauthorized use of a trademark in connection with goods and/or services in a manner that is likely to cause consumer confusion about the source of the goods or services).

⁴⁶ *Id.*

⁴⁷ Rierson, *supra* note 41, at 454.

⁴⁸ Congress did pass the Anti-counterfeiting Consumer Protection Act of 1996, but the law provided no remedies for consumers directly and only gave law enforcement agencies and trademark owners greater weapons. See Pub. L. No. 104–153, 110 Stat. 1386 (codified as amended in scattered sections of 18 U.S.C.).

⁴⁹ Counterfeiters’ increasingly sophisticated manufacturing techniques have enabled them to use falsified markings on counterfeit medicines in connection with genuine medicine, which makes it almost impossible for the average consumer to differentiate between genuine and counterfeit medicine. Most alarming, these counterfeit pharmaceuticals and food products are not regulated, thus providing no certainty that the medicine contains the essential ingredients necessary to fight illness or even that it’s safe for human consumption. These products pose a significant threat to consumer health at both the individual and community levels, potentially resulting in critical treatment failure and community-wide increases in microbial resistance. See

THE SOLUTIONS

To address these issues and simultaneously strengthen effective enforcement efforts while minimizing ineffective enforcement efforts, manufacturers call for the following solutions:

- Congress should clarify the legal doctrine of contributory liability for trademark infringement by unambiguously defining the doctrine and its parameters by statute, including setting forth judicial review standards that encourage courts to develop critical fact-specific case law.
- Congress should update current laws to improve the definition of counterfeits and fill statutory gaps that prevent effective enforcement against counterfeiters. U.S. law must better recognize that the determination of whether a product is a “counterfeit” for purposes of liability should be based on more factors than simply whether the mark is “substantially indistinguishable” from a registered trademark.⁵⁰ Counterfeiters, for example, should not be able to avoid liability simply by changing a letter in a word or slightly altering a symbol, given the potential harm to consumers and brand owners.⁵¹ Necessary updates include the following:
 - Broadening the definition of a “counterfeit mark” to include not just those that are “identical” or “substantially indistinguishable,” but also those whose use is “likely to cause confusion, or to cause mistake, or to deceive” in relation to a registered trademark and where the infringing party “knowingly or willfully engaged in the action.” That broader definition would make statutory damages, not just actual damages, available to a wider range of counterfeiting victims.
 - Encouraging courts handling counterfeiting cases to consider additional factors beyond just similarity of marks, such as a defendant’s intent and risk of harm to consumers in determining whether a mark is a counterfeit and determining damages. Courts almost uniformly consider a defendant’s intent when determining whether a likelihood of confusion exists in the context of broader trademark infringement cases. Consideration of a defendant’s intent seems even more appropriate when determining whether to subject a defendant to the severe penalties associated with counterfeiting.
 - Adjusting available penalties and remedies according to type of counterfeit and nature and degree of deception to better reflect the danger to the public and degree of moral culpability associated with such conduct.
 - Providing consumers with an avenue for relief under federal law when, as is the case in many scenarios, the consumer is the primary victim of counterfeiting activity and suffers severe injury as a result.
- Congress and relevant federal agencies should hold e-commerce platforms to the same standards as brick and mortar retailers. Online virtual shelves should not escape regulators’ scrutiny for failing to closely monitor for fake and untested goods, while physical shelves face intense scrutiny and, in some instances, steep penalties. For example, Congress should revise the definition of “retailer” under consumer product safety laws to ensure e-commerce platforms are required to fulfill the same legal obligations as brick and mortar retailers, including having to report known product-related injuries to the Consumer Product Safety Commission.⁵²
- Congress and Customs and Border Protection should ensure full implementation and enforcement of the STOP Act of 2018, including requirements for the U.S. Postal Service to collect advanced electronic data for 100% of packages to track counterfeits.
- The State Department and the U.S. Ambassador to the United Nations should ensure that low terminal dues for foreign countries do not continue to allow coun-

COUNTERFEIT PHARMACEUTICAL INTER-AGENCY WORKING GROUP REPORT TO THE VICE PRESIDENT OF THE UNITED STATES AND TO CONGRESS (2011), https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/IPEC/Pharma_Report_Final.pdf.

⁵⁰ 15 U.S.C. § 1127.

⁵¹ “Another common scenario occurs when infringers register a similar mark and manufacture goods under this brand. The cost of registration is relatively low and such counterfeiting is rampant.” *How to combat counterfeiting*, WORLD TRADEMARK REVIEW (May 1, 2017), <https://www.worldtrademarkreview.com/anti-counterfeiting/how-combat-counterfeiting>.

⁵² Congress should revise the definition of “retailer” under the CPSA (15 U.S.C. § 2052(a)(13)) to explicitly include e-commerce platforms.

terfeiters to cheaply ship goods to consumers through the U.S. Postal Service.⁵³ They should closely monitor global implementation of the September 2019 agreement by parties to the Universal Postal Union to allow countries to self-declare postal rates and work with the White House on further actions to take if that implementation is insufficient.

IMPROVE GOVERNMENT COORDINATION TO TACKLE COUNTERFEITS

No single federal government agency is primarily focused on, or primarily responsible for, addressing counterfeiting.

More than 20 federal agencies and numerous additional state and local government agencies have jurisdiction over some aspect of counterfeiting.⁵⁴ These agencies do not fully coordinate their activities, resulting in duplicative efforts, wasted resources and gaps that counterfeit products can slip through.

NIPRCC and the White House Intellectual Property Enforcement Coordinator are important players in attempts to better coordinate these efforts, but gaps persist. Counterfeiters have been able to probe weak spots in certain agencies—such as government procurement channels—to spread counterfeit goods.

Those government agencies also do not always effectively coordinate with industry. In a 2018 report, the U.S. Government Accountability Office identified coordination and information sharing between government enforcement agencies and private sector entities as critical to fighting counterfeits.⁵⁵ Manufacturers continue to see gaps in the ability and willingness of government entities to share enforcement intelligence with private sector actors.⁵⁶ Additionally, many manufacturers, particularly small and medium-sized firms, have not taken advantage of opportunities to train or partner with government agencies in order to more effectively block counterfeits. In some cases, they are unable to do so because of limited time and resources.

THE SOLUTIONS

To address these issues, manufacturers urge the U.S. government to take a number of key steps:

- Congress should establish and fund a new White House agency that holds primary responsibility for U.S. anti-counterfeiting efforts, including strategy, policy and enforcement. The new White House agency should serve as a central point of contact for the private sector and other stakeholders, and should:
 - Have a permanent staff to support its operations and dedicated funding for its operations, as well as to allow grants to other U.S. government agencies for anti-counterfeiting activities and programs.
 - Assume anti-counterfeiting responsibilities currently tackled by existing White House offices, including the Intellectual Property Enforcement Coordinator.
 - Have the authority to work with the director of the Office of Management and Budget and the heads of departments and agencies to identify programs that contribute to anti-counterfeiting efforts. It should advise OMB as to whether agency budgets for anti-counterfeiting activities are sufficient to meaningfully address the issues.

⁵³“Terminal dues is the system that posts use to pay one another for international deliveries of letters and small packages. The global terminal dues system, updated every four years by the Universal Postal Union (UPU), does not fully reflect actual domestic processing and delivery costs.” U.S. POSTAL SERVICE OFFICE OF INSPECTOR GENERAL, TERMINAL DUES IN THE AGE OF E-COMMERCE (December 14, 2015), <https://www.uspsig.gov/sites/default/files/document-library-files/2015/RARC-WP-16-003.pdf>.

⁵⁴See *Fake Imports Entering the U.S.: List of federal government agencies working to prevent the entry and distribution of counterfeit and pirated goods in the United States*, INTERNATIONAL TRADE ADMINISTRATION (last visited June 17, 2020), <https://www.stopfakes.gov/Fake-Imports-Entering-the-US>.

⁵⁵See, e.g., GAO–18–216, *supra* note 5, at 40 (recommending that “CBP, in consultation with ICE, should assess what, if any, additional information would be beneficial to share with the private sector and, as appropriate, take action to enhance information sharing”).

⁵⁶For example, despite language in the Trade Facilitation and Trade Enforcement Act of 2015 granting U.S. Customs and Border Protection (CBP) with explicit authority to share certain information with the private sector, CBP has not taken the necessary steps to implement that authority. See *id.* Similarly, CBP does not consistently share information with online platforms about counterfeit products seized at the border that are bound for the platform-run fulfillment centers or that may have been sold via their platforms. See Brian Huseman, VP, Public Policy, Amazon, Comment Letter to Department of Commerce re Report on the State of Counterfeit and Pirated Goods Trafficking and Recommendations (Docket No. DOC 2019 0003) (July 29, 2019), <https://www.regulations.gov/document?D=DOC-2019-0003-0083>.

- Head a newly created interagency task force consisting of representatives at the deputy secretary or deputy director level from key Cabinet agencies and independent agencies (such as the Federal Trade Commission and the CPSC). The task force should also include subgroups focused on anti-counterfeiting strategy, policy and enforcement.
- U.S. government agencies, at the direction and under the oversight of the new White House agency, should expand informational resources to help manufacturers battle counterfeiting, equipping manufacturers and other private sector actors with better information on bad-faith actors as well as on trusted importers. These should include databases and tools to facilitate the exchange of risk assessment information and lists of known violators between government agencies, private sector actors and the general public. Specific efforts should include the following:
 - CBP development of a database and resource library on importers that CBP has vetted and deemed to be “trusted.”⁵⁷
 - CPSC use of its National Electronic Injury Surveillance System to identify product injuries and deaths from counterfeit products and report those trends to enforcement agencies.
 - CPSC establishment of a substantial product hazard list, as permitted under the Consumer Product Safety Improvement Act, that could provide critical tools to battle fake and counterfeit products that have spiked during the COVID–19 crisis.
- U.S. government agencies, at the direction and under the oversight of the new White House agency, should eliminate structural and practical barriers that limit government-industry information sharing:
 - CBP should fully and promptly implement the authorities granted to CBP under the Trade Facilitation and Trade Enforcement Act of 2015 to share information consistently with private sector actors on suspected counterfeit goods that have been seized or abandoned.
 - CBP should take steps to expand the level of information consistently shared with the private sector, such as more limited redaction of photographs of suspected seizures to better allow identification of counterfeit products.
 - CBP should revise internal procedures to make it easier for border agents to provide brand owners with samples of seized products. This would allow brand owners to more quickly take action and work with authorities to get the counterfeits out of circulation.⁵⁸
 - CBP and other U.S. government agencies should promote, facilitate and provide financial incentives for companies, particularly small and medium-sized companies, to share information with Customs officials on how to identify genuine manufactured products.
 - CPSC should improve procedures to improve the speed and effectiveness of processes to quickly share reliable counterfeit-related consumer safety incidents with CBP and other relevant agencies. CPSC should also prioritize hiring necessary staff in support of these efforts, which should improve the U.S. government’s ability to identify, track and ultimately seize counterfeit consumer goods.⁵⁹

⁵⁷Such a database was promised under Objective 4.2 (Explore technology options to increase the exchange of e-commerce information) in CBP’s 2018 strategy on e-commerce. See U.S. CUSTOMS AND BORDER PROTECTION, E-COMMERCE STRATEGY 9 (2018), https://www.cbp.gov/sites/default/files/assets/documents/2018-Mar/CBP-E-Commerce-Strategic-Plan_0.pdf.

⁵⁸Under current law, CBP will only release seized product samples to brand owners after they provide CBP with a cash bond intended to insulate CBP from liability. The CBP port director determines the value of the bond on a case-by-case basis. To expedite the process, CBP should streamline the process and allow brand owners to pay through alternative means, such as by credit card. See Bruce Leeds, *U.S. Customs and Border Protection Enforcement of Trademarks*, BRAUMILLER LAW GROUP (October 7, 2018), <https://www.braumillerlaw.com/u-s-customs-border-protection-enforcement-of-trademarks/>.

⁵⁹Section 6(b) of the Consumer Product Safety Act requires the Commission to “take reasonable steps to assure, prior to its public disclosure thereof, that information from which the identity of such manufacturer or private labeler may be readily ascertained is accurate, and that such disclosure is fair in the circumstances and reasonably related to effectuating the purposes” of the CPSA. 15 U.S.C. 2055(b)(1). Manufacturers rely on the safeguards provided by section 6(b) and the Commission’s current information disclosure rules to ensure that information dis-

- Congress should establish a fund, at the direction and with oversight of the new White House agency, to support development of new technologies, products and best practices to detect and block counterfeit versions of products needed for responding to COVID-19 and future pandemics.

IMPROVE PRIVATE SECTOR COLLABORATION IN THE FIGHT AGAINST COUNTERFEITS

THE CHALLENGE

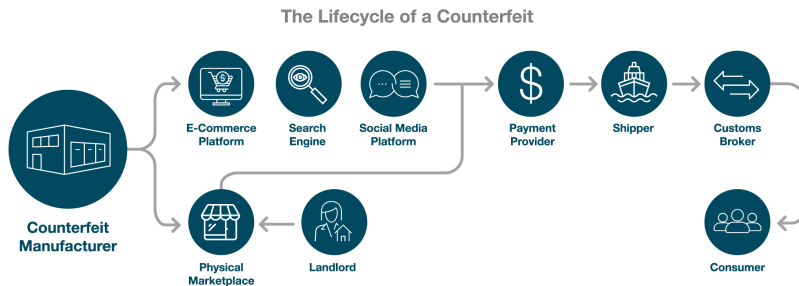
Private sector actors, including brand owners, online marketplaces, third-party search providers, shippers, customs brokers and payment providers, bear the brunt of the impact of counterfeiting activity. It is manufacturers’ brands that are infringed, e-commerce platforms that are hijacked to support illicit activity and payment platforms that are misused to facilitate payments. While there is an important role for government entities to take action against counterfeiting, the private sector can also drive effective solutions to this growing challenge.

Despite the obvious need for robust private sector cooperation, multiple factors have made collective efforts to find solutions more challenging. Global counterfeiting has grown faster than the resources of individual private sector stakeholders, and new counterfeiting tactics have challenged the ability of individual stakeholders to adapt and develop new, common approaches to the problem.

A lack of information sharing among private sector entities, particularly brand owners and e-commerce platforms, has weakened the ability of all stakeholders to monitor and fight against fake products and detect bad-faith vendors that hide their real identity or move from platform to platform.

No single company or sector can fight counterfeiting alone. Legitimate manufacturers hold the information necessary to distinguish their products from the fakes on the market. E-commerce platforms hold information about the third-party sellers dealing in fake products. Search providers have a broad view of how actors can move across different platforms. Payment providers are a critical piece of tracing illicit gains to counterfeiters and cutting off their access. Input from each of these sources is necessary to allow both the government and private sector to have full insight into the paths of counterfeit goods and to track those responsible.

Manufacturers must collaborate with other legitimate companies to fight counterfeiting, seeking common approaches and sharing best practices. All private sector stakeholders must develop concrete mechanisms, including new standards, databases and programs, to share information directly and regularly about counterfeit products and bad-faith vendors. They must use that information to limit the supply of counterfeit products and to continually improve their strategies and mechanisms.



THE SOLUTIONS

To address these issues, manufacturers urge private sector stakeholders to take a number of key collaborative steps to better fight counterfeiting:

- Private sector actors should develop new mechanisms for collaborative information sharing on counterfeiting activity. These mechanisms should include data on counterfeiting activity and specific actors that can be used by platforms to im-

closed publicly is accurate and fair. Reasons for the public disclosure of information by the Commission include, but are not restricted to, responses to Freedom of Information Act and media requests. The CPSC also may seek to disclose information on its own.

prove vendor vetting and by legitimate manufacturers to pursue enforcement action against bad actors. Such mechanisms could take the form of databases, exchanges or dialogues, and they should make it easy for all stakeholders to share information, based on a common set of information, and to make that information fully searchable and accessible.

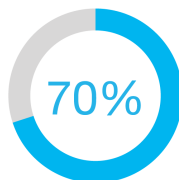
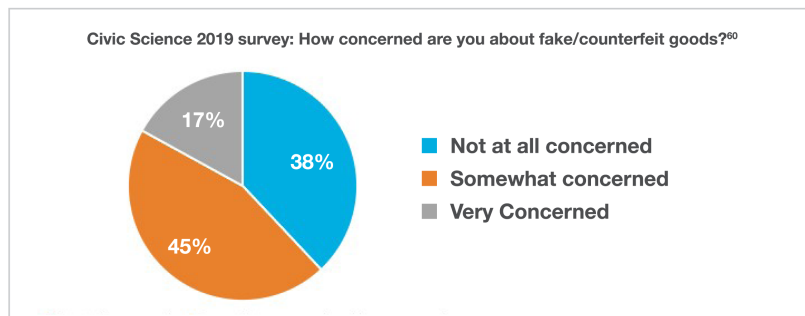
- Private sector actors should work collectively to improve platform brand protection programs, expanding the scale, accessibility and scope of action for these programs. In particular, the following actions are needed:
 - Improve the accessibility of existing brand protection programs for all manufacturers by expanding their scope and ensuring that the terms and conditions for participation do not effectively block out any group of brand owners, including small and medium-sized manufacturers.
 - Create new programs or certifications, such as “official” or “verified” product listings, and mark products and vendors that have fully verified that they are not counterfeit. For example, use of specific domain names such as the pharmacy domain, can distinguish legitimate e-commerce sources from fraudulent sources and provide consumers with access to verified online pharmacies.
 - Strengthen and streamline direct communication channels between platform providers and manufacturers, including by establishing consistent, easy-to-access contacts engaged with and knowledgeable of key industries.
 - Expand the scope of activity for these programs to include joint enforcement activities between platforms and brand owners.

EMPOWER CONSUMERS TO AVOID COUNTERFEITS

THE CHALLENGE

In addition to new enforcement tools and brand protection programs, addressing the fundamental challenge of counterfeits requires all parties to equip consumers with the tools to avoid purchasing them in the first place.

Consumers are not sufficiently aware or concerned about the direct danger that counterfeit products can pose—not just to businesses, but directly to themselves. Even when customers are aware of the negative impacts of counterfeiting, they may not associate them with a direct personal risk to themselves and those around them.



More than 70% of online shoppers in a recent survey expressed current or possible concern about the purchase of counterfeit products via Amazon.⁶¹

Even consumers aware of the risk of counterfeit products can fall victim to counterfeiting by unwittingly purchasing fake products online. Surveys indicate that consumers are more aware of, and concerned with, counterfeit products being sold online but are nonetheless worried about their ability to spot counterfeit products.

That task is only getting harder as counterfeiters get smarter. Not only are counterfeiters continuing to produce fake products that are closer matches to the original version, but they are also increasingly savvy in utilizing the online environment to make consumers believe they are buying genuine products. For example, a counterfeiter may advertise with pictures of the genuine product while shipping customers the fakes. Counterfeiters have also gotten smarter at removing “red flags” that consumers may use to tell a real from a fake product, including pricing discrepancies, online reviews or suspect language used to describe the product.

With a crowded media environment, increasing sophistication among counterfeiters and the rapid growth in e-commerce, the traditional playbook is not enough. Consumers expect everyone, including manufacturers, online marketplaces and social media platforms, to do more to protect them against the danger of fake products.⁶²

Legitimate manufacturers and platforms alike must invest in new campaigns, technologies and tools to inform consumers about the direct harm that counterfeit products can have. They must not only educate consumers about the real and direct harm that counterfeits can cause but also provide practical tools to help consumers differentiate between real and fake products. They must increase and improve communication with consumers if they have purchased known or possible counterfeit products and warn potential buyers away from sellers or websites with a track record of selling or facilitating counterfeits.

THE SOLUTIONS

To lower demand for counterfeits, Congress should take action to help manufacturers and other stakeholders address these needs:

- Congress should pass legislation requiring platforms to notify online shoppers about actual or potential purchases of counterfeit goods. If they do not take such steps, they could face contributory liability for infringement due to vendor activities on their platforms. To avoid such liability, platforms should develop specific protocols based on consultation with private sector stakeholders. They should communicate directly with customers that have purchased known or suspected counterfeit products and develop specific warning signals to flag when directing customers to sellers or websites previously engaged in, or reasonably suspected to be engaging in, counterfeit activity.
- Congress should appropriate emergency funds to the Department of Health and Human Services to oversee a public campaign to educate consumers of the dangers of fake and counterfeit versions of products used for the treatment or prevention of COVID-19:
 - The campaign, run either directly by government agencies or through grants to private sector groups, should develop and disseminate content that is clear, focused, easily digestible and tailored to the online environment to reach those most likely to purchase fake COVID-19 products through online platforms and social media websites.
 - The campaign should include a dedicated, continually updated COVID-19 anti-counterfeiting resource developed in consultation with e-commerce platforms, brand owners and law enforcement agencies. This resource would rapidly inform consumers about the dangers of counterfeit products and how to identify, report and protect against fake products during the health crisis, and inform U.S. government responses to future health crises.

⁶⁰Danielle Commisso, *Men and High-Earners Are More Likely to Buy Counterfeit Goods*, CIVICSCIENCE (August 13, 2019), <https://civicscience.com/men-and-high-earners-are-more-likely-to-buy-counterfeit-goods/>.

⁶¹CPC STRATEGY, *THE 2019 AMAZON CONSUMER SHOPPING STUDY: HOW SHOPPERS BROWSE AND BUY ON AMAZON 14* (2019), <https://learn.cpcstrategy.com/rs/006-GWW-889/images/2019-Amazon-Shopper-Survey.pdf>.

⁶²For example, 63% of respondents in a private-sector survey of more than 2,600 global online shoppers indicated that they “didn’t think enough was being done by brands, social media platforms and online marketplaces to protect them from counterfeiters, fraud and cybercrime.” See MARKMONITOR, *SOCIAL MEDIA: INSIGHTS INTO CONSUMER SHOPPING BEHAVIOR 12* (2019), https://markmonitor.com/wp-content/uploads/dlm_uploads/2019/09/Global-Online-Protection-Business-Survey-Q3-2019.pdf.

III. Conclusion

The current COVID-19 pandemic and the countless headlines about fake test kits, counterfeit face masks and fake drugs underscore the counterfeiting challenge. But this problem extends beyond health products. It also affects manufactured products that American households use every day, from auto parts to clothing to toys. Counterfeit versions of many products are widely available to American consumers, particularly through e-commerce platforms. These counterfeit goods pose a triple threat: harming the safety and well-being of consumers, limiting the competitiveness of manufacturers of all sizes and undermining American innovation.

Manufacturers need real, actionable, innovative policy solutions that reverse the rising tide of counterfeit products. This report provides a series of clear, decisive actions that all stakeholders can take, in government and in the private sector, to stop counterfeiters in their tracks.

The time is now. The solutions are clear. We must act.

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The Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the Senate Finance Committee’s hearing titled “Part 2: Protecting the Reliability of the U.S. Medical Supply Chain During the COVID-19 Pandemic” scheduled for July 30, 2020. We applaud the leadership of Chairman Grassley, Ranking Member Wyden and members of the Committee for holding this hearing to examine the integrity of our nation’s medical supply chain.

Background on Premier

Premier Inc. is a leading healthcare improvement company, uniting an alliance of more than 4,000 U.S. hospitals and health systems and approximately 175,000 non-acute providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, and consulting and other services, Premier enables better care and outcomes at a lower cost.

Premier works around the clock with the nation’s hospitals and other healthcare providers, suppliers, distributors and federal and state agencies to ensure products get into the right hands so every patient gets the care they need. Given Premier’s unique position in the supply chain as an extension of America’s healthcare providers, we understand firsthand the impact to patient care when hospitals and health systems do not have access to the drugs and medical supplies needed to treat patients. The coronavirus outbreak underscores what Premier has been advocating for the better part of a decade—that the U.S. must be more forward-looking and strategic about our supply chain. When the system works, no one thinks about it, but in an outbreak, vulnerabilities are on display.

Premier has been a longstanding advocate for supply chain diversity and resiliency, taking lessons learned from disasters and past outbreaks such as Ebola and H1N1. Creating permanent solutions to ensure a reliable supply of critical medical supplies and drugs has been the mission of Premier since day one. We need, however, policy changes for us to continue to succeed in our work. It is critical that Congress act now to proactively address known supply chain vulnerabilities.

Premier’s Leadership in 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 identify and implement innovative solutions that 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. To meet the unprecedented demand, Premier

- Used our global sourcing arm, S2S Global, to identify new sourcing of manufacturing capacity, ultimately contracting with seven different PPE factories across the globe to secure 36 million masks and respirators and 16 million gowns.
- Arranged cargo carriers and major airlines to expedite transportation of products so they could be onshore in hours, rather than months.
- Coordinated and allocated 2 million donated masks.

- Added 40 new manufacturers of COVID-19 related supplies to our national contracts using an expedited review process to rapidly increase options.
- Worked with non-traditional and adjacent industries such as distilleries, textile manufacturers, and automobile manufacturers to fill supply gaps for essentials such as hand sanitizer, isolation gowns and surgical caps.
- Created an online exchange for health systems, Resilinc, to trade PPE supplies among one another, dynamically moving specific supplies to the neediest hot spots.
- Partnered with 15 health systems to acquire a minority stake the nation's largest domestic supplier of PPE, Prestige Ameritech, such as masks and N95s.
- Leveraged our existing drug shortage program, ProvideGx, to secure additional safety stock and dedicated supplies, thereby avoiding shortages for many critical products.

In addition, Premier also worked closely with the Administration to provide data on surge demand, clinical utilization, and barriers to providing care and improving healthcare delivery during the pandemic. This work resulted in numerous waivers, regulatory flexibilities, and guidance documents that were critical during the public health emergency to prevent infection, avoid unnecessary hospitalizations for ambulatory conditions, increase availability of PPE and medical supplies, and more.

Finally, Premier played the leading role in the creation of the COVID-19 Private Sector Supply Chain Coalition, which was established to coordinate an integrated, public/private supply chain response to the challenges created by the COVID-19 pandemic. The Coalition serves as a single coordination point to share non-competitive, non-pricing information, best practices and strategies among key parties in the healthcare supply chain to promote the efficient management of supply and distribution during the COVID-19 pandemic. The Coalition's primary goals are to promote public and private sector cooperation, strengthen the healthcare supply chain, and speed answers to urgent supply challenges across hospitals and other U.S. healthcare providers.

Premier's Reflections and Learnings From COVID-19 Response Efforts

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.
 - Timely and regular access to government leaders and openness to input.
- Elements that Led to the Current Situation:
 - 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 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, nursing homes, and others.
- 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.
- Design stockpiles to create coordination rather than competition between state, local and national stockpiles. Stockpiles should be customized to meet the unique needs of various healthcare sectors, such as nursing homes.
- 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.
- Develop a real-time national syndromic surveillance system that also includes real-time supply chain demand data so that there is a means to identify a disease threat as early as possible as well as its implications on healthcare resources.
- 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.

Maintaining Supply Chain Integrity

During the pandemic, unfortunately a 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 thereby challenging the integrity of the medical supply chain.

Premier divides the gray market into two categories:

- Alternative suppliers → Legitimate product but not acquired through traditional entity in the supply chain at an elevated price. For example, N95 masks being sold at \$3–\$5 per piece whereas they normally cost \$0.30–\$0.40 per piece.
- Black market → Fraudulent, adulterated or counterfeit products at an elevated price. For example, quantities of product being offered that are physically unable to be legitimate such as an offer for 2 billion medical grade N95 masks that would normally require 10+ years to manufacture.

The emergence and continued presence of the gray market is directly related to supply chain stresses adding complexity and confusion for supply chain experts and clinicians questioning if their PPE is adequate to protect them, their patients, and

their families. In the past month, Premier has noted an increase in gray market actors with increasingly sophisticated plans rendering themselves nearly undetectable.

Throughout the pandemic response, Premier has been diligent in warning health-care providers of the risks associated with gray market purchases and has been prudent in our response which includes vetting over 2000 gray market solicitations through (1) review of submitted documentation to evaluate business and clinical certifications; (2) clinical evaluation of the product including raw materials, production facilities, and documented integrity of their supply chain; and (3) evaluation of the business itself. To date, less than 15% of gray market solicitations have passed Premier's stringent vetting process and were considered legitimate alternate suppliers.

To help strengthen and maintain the integrity of the supply chain during this and future pandemics, Premier recommends the creation of a centralized clearing house to vet gray market offers and test products to ensure integrity. The clearing house should:

- Hold all payments in escrow until testing is validated;
- Test lot samples through a certification process;
- If the product is validated, it should be permitted for sale;
- If the product is not validated; it should be confiscated, and appropriate action be taken against the gray market actor.

Revamping 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:

- The SNS should maintain a minimum of a 90-day supply of critical medical supplies and drugs based upon surge demand from hot spots such as New York, Washington, Detroit, etc.
- The current process for accessing the SNS is cumbersome and state specific. Working alongside private sector partners, the Administration should create a streamlined and efficient process for accessing drugs from the SNS.
- The SNS should work proactively with GPOs to forecast demand and increase capacity/supply to avoid shortages.
- The SNS should work with GPOs to rotate soon-to-expire stock out of the SNS and into health systems at a discounted rate. This rotation is supposed to occur, but GPOs can make this happen and will ensure the SNS is continuously stocked with in-date products and allow the SNS to recoup some of their expenses associated with purchase of these products.
- The SNS should be transparent regarding distribution of supplies and drugs from the SNS. The SNS should provide, at minimum, a detailed monthly report of what supplies were distributed to where and in what quantities. During a public health emergency, reporting should occur weekly.
- The SNS, as well as state and local stockpiles, should be encouraged to purchase off GPO contracts to help aggregate purchasing volume and keep prices competitive.
- The SNS should work to ensure that critical medical supplies and drugs are located as close to the delivery of care as possible. This includes exploring opportunities to leverage health system warehouses in major metropolitan areas or in rural areas.
- Create a customized stockpile for nursing homes with appropriate supplies, drugs and other needs.

- Include health systems or regional buying groups as potential stockpile operators. These organizations would be responsible for managing the stockpile for the providers in a region. This would allow an efficient means to rotate inventory and assure accountability for the stockpile.

Incentivizing Domestic Manufacturing

To increase domestic manufacturing of critical medical supplies and drugs, 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. To incentivize domestic manufacturing, Premier recommends Congress consider the following policy proposals:

- Section 3101 of the CARES Act requires a report by the National Academies of Medicine (NAM) on the foreign reliance on manufacturing for critical healthcare supplies, the risk to national security, and recommendations for improving the resiliency of the supply chain. However, these recommendations are not expected to be available in the near future and, therefore, Congress should accelerate the development of this report to strengthen domestic manufacturing in the long-term.
- Offer 0% interest loans to manufacturers of critical medical supplies and drugs to incentivize increasing domestic manufacturing capacity. (for example—investing in automation to offset labor costs).
- Offer tax incentives to manufacturers of critical medical supplies and drugs to incentivize increasing domestic manufacturing capacity, similar to incentives provided during the 1980s and 1990s to incentivize manufacturing in Puerto Rico.
- Ensure there is at least:
 - One domestic supplier of the final form, ancillary products and raw materials for critical medical supplies and drugs.
 - 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.
- Incentivize the domestic farming/cultivation of raw materials needed for critical medical supplies and drugs.
 - For example: cotton for PPE and swabs, pigs for Heparin, poppy for sedatives, etc.

Expanding Disease Surveillance to Detect, Identify, Model, and Track Emerging Infectious Diseases

COVID-19 has exposed one of healthcare’s fundamental weaknesses: the fragmented and siloed nature of care delivery and the lack of centralized coordination when it comes to managing and preventing disease spread. The public health system continues to rely on flawed data and obsolete technology that consistently fails to accurately identify and track current cases, monitor disease progression, or predict future surges. Not only do these blind spots create opportunities for the disease to spread, they also undermine the ability to safely plan for economic recovery and re-opening of the country. Unfortunately, issues related to underfunding of and improvements to the public health infrastructure are not new.^{1, 2, 3}

There is a limited ability to nationally track symptoms of the pandemic, which would provide lifesaving insights as many as seven days before a patient is hospitalized with COVID-19. This inability to detect and respond is a critical missing “gating step” called for in the “Opening of America” to re-starting the economy and keeping it open. Instead, the preference has been to rely on testing, which has significant limitations. Americans need confidence that there is a means to identify a new COVID-19 surge as early as possible to allow effective containment and mitigation without adding billions in costs to national, state, and local budgets. The COVID-19 emergency underscores the need for real-time syndromic surveillance, providing an upstream alternative to identifying cases before tests can detect them or patients are hospitalized.

¹ Institute of Medicine 2012. For the Public’s Health: Investing in a Healthier Future. Washington, DC: The National Academies Press. <https://doi.org/10.17226/13268>.

² DeSalvo KB, Wang YC, Harris A, Auerbach J, Koo D, O’Carroll P. Public Health 3.0: A Call to Action for Public Health to Meet the Challenges of the 21st Century. *Preventing Chronic Disease* 2017;14:170017. DOI: <http://dx.doi.org/10.5888/pcd14.170017>.

³ <https://www.astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Public-Health-and-Information-Sharing-Toolkit/Collection-Use-Sharing-and-Protection-Issue-Brief/>.

Conclusion

In closing, the Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the Senate Finance Committee hearing on the integrity of the medical supply chain. As an established leader in the healthcare supply chain, Premier is available as a resource and looks forward to working with Congress as it considers policy options to continue to address this very important issue.

If you have any questions regarding our comments or need more information, please contact Soumi Saha, Senior Director of Advocacy, at soumi—saha@premierinc.com or 732-266-5472.

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Shirley Byrd, Chairman
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July 28, 2020

Honorable Chuck Grassley
Chairman

The Honorable Ron Wyden
Ranking Member

Committee on Finance United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Senators Wyden and Grassley,

As Administrator of Hill Hospital, located in rural Sumter County, one of Alabama's poorest counties, I am proud of our response to COVID-19 despite the unprecedented challenges we faced due to the limited amount of personal protection equipment (PPE) at the onset of the COVID 19 pandemic.

I recall when Sumter County got its first case in March, our staff began to panic. Our doctors, nurses, and office staff questioned, "What are we going to do?" "How can our patients be protected? How can we be protected?" With very little PPE in-house, our small 27-bed and 4-emergency room facility began preparing for the worse.

We had a mere three weeks of PPE, so we immediately reached out to increase our stock; but we quickly ran into difficulty when we learned that our primary suppliers, Cardinal Health and Medline, had everything on back order. As our stock began to dwindle, our maintenance director of 40 years remembered that the hospital had a stockpile of PPE resulting from previous emergency preparedness efforts. That discovery would be our saving grace through March and April.

However grateful for this discovery, we again experienced a decline in PPE in May and June due to an increase in emergency room patients. Within two months, we had more than 300 patients presenting to the ER with COVID-19 symptoms, confirming 15 of them to be positive.

By then, we were managing our PPE by keeping a small par level in each department, utilizing a sign-in-sign out system, and requiring nurses to reuse N95 masks for up to 5 days when they were not soiled or torn. Doctors and nurses expressed their concerns as many have comorbidities and are over 60. They were afraid of putting their lives at risk. To ensure safety, we began screening patients outside in a tent, which helped prevent an influx of patients and required minimum use of PPE.

The high demand for PPE has caused small rural hospitals like ours to question the integrity of our suppliers. While supplies from the State distribution center and other businesses have allowed for our continued day-to-day operation, the scarcity of resources from our usual suppliers is worrisome. Orders that were placed with these vendors in March still have not been filled. As a result, I am having to store PPE in my office to prevent exhaustion of our current supply.

PPE continues to be a serious concern for Hill Hospital. Without continuous access to these critical items, safety for both patients and our front-line providers is greatly jeopardized. Currently there are 354 confirmed cases with 15 deaths in Sumter County, according to the Alabama Department of Public Health. We are fearful of not being able to adequately service our community due to lack of PPE as COVID-19 continues to spread and the cold and flu season approaches.

Funding from the CARES Act has helped address some of our PPE shortage, allowing us to purchase supplies, although at much higher prices, from suppliers outside our normal purchasing group and to purchase at levels above our historical volume. Additionally, we have utilized this funding to create a safer environment for patient care by converting multiple isolation rooms with negative pressure.

Every day when I enter the halls of Hill Hospital, I am met with the faces of employees who are depending on me to ensure we maintain during and after COVID-19. I want to deliver; however, I need the appropriate resources to do so.

To this end, I am recommending that Congress consider the following:

- Guarantee that small rural hospitals have access to affordable PPE through private vendors, regardless of the volume of our orders;
- Continue to ensure that the State of Alabama receives the resources needed to help with the supply of PPE to the rural hospitals in our state; and
- Continue to fund rural hospitals post COVID-19 to prevent closure.

Over the past 6 years, Hill Hospital has had to make drastic changes to remain financially viable. Among other measures, we have decreased the hours and salaries of our staff and eliminated non-essential services. Just as we were experiencing a turnaround, a beacon of light, COVID-19 happened. I am fearful, that our small hospital will not be able to withstand the unprecedented financial pressure placed on us by COVID-19 without assistance from the federal government.

Again, I am very proud of the professionalism and commitment of the doctors, nurses, and staff of Hill Hospital, and I remain dedicated to ensuring the safety of these employees who put their health on the line every day to ensure that the residents of Sumter County receive the high level of care that they deserve.

If you have questions or need additional information, please feel free to contact me at 205-376-6400 or by email at lwilson@hillhospital.org.

Sincerely,

Loretta Wilson, MBA/HCA
Administrator/CEO
Hill Hospital of Sumter County

