

**PART 1: 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 28, 2020
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**PART 1: PROTECTING THE RELIABILITY
OF THE U.S. MEDICAL SUPPLY CHAIN
DURING THE COVID-19 PANDEMIC**

TUESDAY, JULY 28, 2020

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

The WebEx hearing was convened, pursuant to notice, at 10:17 a.m., in Room SD-215, Dirksen Senate Office Building, Hon. Chuck Grassley (chairman of the committee) presiding.

Present: Senators Portman, Toomey, Cassidy, Lankford, Daines, Wyden, Stabenow, Cantwell, Menendez, Carper, Cardin, Brown, Bennet, Casey, Warner, Hassan, and Cortez Masto.

Also present: Republican staff: Daniel Boatwright, 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. Good morning. I would like to welcome everyone to the Finance Committee hearing. The title is very appropriate at this time of the COVID-19 pandemic: the reliability, and protecting it, of the U.S. medical supply chain.

This is our very first hearing to discuss the integrity of our Nation's medical supply chain. Today, we will hear from the Department of Homeland Security, and in a few days we will hear from private-sector stakeholders.

It is Congress's responsibility to ensure that DHS upholds its responsibility to protect the public health by properly ensuring that Americans on the front line get safe and effective medical supplies.

I think we can all agree: the COVID-19 pandemic has exposed several vulnerabilities of our medical supply chain. Some of these vulnerabilities are new, while others have been around a long time before the pandemic and have been further exacerbated with this virus crisis.

Indeed, I have been asking questions long before the pandemic brought these issues to the forefront. In November of last year, I finalized my oversight activities on the proliferation of counterfeit and other illicit goods sold on e-commerce platforms.

The ranking member and I issued a report on our findings and highlighted the threat counterfeits pose to our Nation's economic

security, and the health and safety of our populace. We also highlighted that many counterfeits originate in China and Hong Kong. At this point, I think it is fair to say that China has serious quality-control problems. It was evident then, and the pandemic has proved it more so. Before the virus pandemic, hospitals and health-care workers could avoid purchasing counterfeits by tapping into their traditional supply chains.

However, as the demand for personal protective equipment skyrocketed, some of these providers have had to go outside of this normal supply chain to source supplies elsewhere, and in some cases the supplies that have inadvertently been purchased are fake, faulty, or even illicit medical supplies.

The problem of counterfeit and faulty products is something that I have looked into for a very long time, dating back even to my days as chairman of the Judiciary Committee. As the virus began its foothold in the United States, I also sent a letter to Vice President Mike Pence and several other agency heads to express my concern that PPE shortages were allowing bad actors to take advantage of hospitals and health-care workers desperately seeking supplies.

I have talked to hospitals around the country, and particularly in Iowa, and have heard stories of price gouging, shady middlemen, and personal protective equipment that was ordered and then never even arrived, or if it did, was unusable. In my letter, I asked the administration to take this issue seriously and to prosecute bad actors.

Today, we will hear from a representative of the U.S. Immigration and Enforcement's Homeland Security Investigations on their efforts to do just that.

Before we hear from today's witnesses, I would like to discuss the substance of today's hearing. First, I want to go back to the beginning and expose the root cause of why the United States—and frankly, the world—is experiencing a breakdown of their supply chains.

China is the largest manufacturer of personal protective equipment in the world. More than 40 percent of these supplies are manufactured there.

In the beginning of the pandemic, China did what was, we would now consider unthinkable—I do not know what they thought about it—they turned off the taps of PPE manufacturing and heavily restricted their export. The Chinese Government also directed its local and state governments to source more supplies from the international market. As global demand soon spiked and China restricted exports, distributors and suppliers were unable to fulfill orders. As a result, some hospitals report estimates of delays of 3 to 6 months for supplies.

Some pundits say China did what it did to address a domestic health crisis. However, it is important to remember that in the beginning China downplayed the seriousness of the virus threat to the world while it redirected vast quantities of PPE towards its domestic needs. In the United States, China's decision to redirect medical supplies occurred when States, territories, localities, and tribes began to desperately need these critical supplies.

While China has since reversed course and allowed PPE to leave the country, the United States has continued to struggle to meet demands, with most of our supply chains heavily dependent yet on China or Mexico.

We cannot allow our supply chains to be so heavily reliant upon other countries. I look forward to working with my colleagues, both Republican and Democrat, to discuss how we can diversify our supply chains, and particularly do it by increasing manufacturing in the United States.

Before the pandemic hit, hospitals and health-care providers employed a “just-in-time” approach to sourcing supplies from trusted distributors. However, as the virus gained a foothold in our country, everyone rushed to compete for supplies. That tremendously exacerbated the shortage.

As a result, some health-care providers resorted to purchasing PPE from unverified suppliers, and some even turned to the Internet to get supplies. By doing so, these providers sometimes received fake, fraudulent, or even illicit goods not safe for use in treating patients with the virus. In other cases, providers faced price gouging or hoarding.

Fake N95 masks have become so prolific that 3M recently filed suit against several purported PPE suppliers profiting from COVID-19 at the expense of our vulnerable people.

Large health-care systems have told me that the supply chain is doing better now, with more PPE coming in daily, which gives them the ability to avoid unverified suppliers. However, smaller providers continue to face shortages which may cause them to continue to go to these unverified suppliers. Even more concerning is that smaller providers, like safety-net clinics and rural hospitals, tend to treat low-income families, a majority of which are African Americans or Latinos. They have been heavily hit by the pandemic.

This population has been hit the hardest, and is four or five times more likely to be hospitalized. This is an issue that cannot be sugarcoated or spun for some political purpose—because it is just plain simply a fact. The black and brown communities are suffering.

As members of the Congress and stewards of the public trust, we must do everything in our power to protect this vulnerable population. This committee is considering several proposals along that line.

And one way that we can help this population is to do everything in our power to shore up the integrity of the Nation’s supply chain and make sure that all hospitals and health-care providers get the quality supplies that they need to treat these patients.

With that said, I now turn to the Department of Homeland Security’s efforts to protect the integrity of our Nation’s supply chain. And our witnesses today will help us do that. DHS and its components are engaged in an unprecedented whole-of-government response to combat the virus pandemic.

Our Nation has not faced something like this in more than 100 years, even though the 1960s had quite a loss of life from flu. Even so, we cannot deny that the Federal Government’s approach to emergency preparedness has always been fraught with problems, going back to previous administrations. This is not some partisan

point. If I said, for instance, it was a problem in the Obama administration, it is a fact. But it does not just start there with Obama.

It also shows that, no matter which party is in the White House, we can always do more to prepare.

Today, we will hear from witnesses who represent the Office of Procurement, U.S. Customs and Border Protection, and ICE's Homeland Security Investigations.

I thank you all for being present today. In closing, I just want to say two things. First, I want to thank the officials who work tirelessly in the Department to ensure the integrity of our Nation's supply chains, and for their efforts to ensure that those most in need get critical quality medical supplies. Your job is incredibly important right now, but it has been a very important job throughout a long period of time.

Second, we must come together to address vulnerabilities in our Nation's supply chain. I hope today we can have a good-faith discussion so that we can better understand what we as a Congress need to do to protect America's front-line workers.

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

The CHAIRMAN. Senator Wyden?

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

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

Mr. Chairman and colleagues, the Finance Committee will hold two hearings this week looking at why State governments and health-care providers have struggled to get the PPE and the gear they need to fight the scourge of the coronavirus.

Now, some members of this committee want this to be all about counterfeits and China. In my view, that story is way off the real mark. If you want to know what is doing the most to contribute to the shortage of personal protective equipment, you have to start with Donald Trump shirking his responsibility to lead, forcing States and hospitals to compete against each other for the supplies they need and exposing them to scammers on the PPE gray market.

From the beginning to this day, the President is walking away from his number one responsibility, which is to keep the American people safe. The pandemic has claimed 150,000 American lives and counting, but instead of focusing on that, the President is launching paramilitary occupations in American cities, including my hometown of Portland. It is all a big campaign-season deflection from the enormous human and economic toll that the pandemic is taking now.

My home State of Oregon is a perfect example of how the Trump administration's priorities are so out of whack. Let me explain why. Back in the spring, the President was in full-on denial mode that he was responsible for helping our doctors and nurses and caregivers and other front-line workers find the PPE and other equipment that they so desperately had needed.

In mid-March, during one of those inimitable coronavirus press briefings, Donald Trump said the government is, and I quote, "not

a shipping clerk” and that when it comes to acquiring PPE, quote, “Governors are supposed to be doing it,” unquote.

His disinterest in leading any kind of coordinated effort to acquire and distribute PPE forced our States to compete against each other on the open market. That gave a lot of room for sketchy suppliers and scam artists to rip off the taxpayers and endanger front-line public health workers with unsafe and substandard PPE.

My home State, Oregon, for example, purchased close to 1 million N95 masks from a supplier in China. After those masks arrived, they were de-certified because they could not pass key safety screenings. The U.S. agency that tests respirators, NIOSH, now says that some of the Chinese respirators they rejected could have been counterfeit, but nobody actually even knows that for sure.

The fact that Oregon, like so many States and medical providers, had to go out on its own and buy critical safety equipment in the middle of a global pandemic is a disgrace. And the pandemic continues to rage in the Pacific Northwest. But Donald Trump is not trying to find new ways to help Oregon deal with this pandemic.

One last point about priorities. I wish Donald Trump would attack the coronavirus half as hard as he is attacking our cities. Instead of his hands-off approach to fighting the coronavirus, Donald Trump is hands-on terrorizing my friends and neighbors at home in Portland with a secret police force of hundreds of paramilitary units.

Night after night, they tear-gas a “Wall of Moms.” One of my personal friends, Sharon Meieran, a county Commissioner and an ER doc who was out protesting peacefully, was gassed without provocation. Peaceful protesters have been shot with impact munitions that are unquestionably capable of killing an individual. People have been snatched off the streets into unmarked cars, holding and interrogating them without justification or charges. And now Donald Trump is saying he is going to take this to other cities—take this violence nationwide.

So what is happening in my State over the last few weeks is just an example of how Donald Trump is neglecting his responsibilities when it comes to fighting the pandemic—and abusing the office for political gain. It is time to get down to the single most important issue, and that is contributing to the personal safety and well-being of the American people from sea to shining sea. And one of the ways you do that is to actually get personal protective equipment into the hands of all the Americans who need it, and not deflecting attention elsewhere.

Lots to talk about today. I look forward to the questions and answers. Thank you, Mr. Chairman.

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

The CHAIRMAN. If we were having this in Des Moines, IA, at the Federal building where my office has been located ever since I have been in the U.S. Senate, and for my predecessor in this position, the Des Moines police department would be defending that building if the same violence occurred there. The Des Moines police department would do that. But if they did not, the people working in that building and the taxpayers who paid for that building, would expect the Federal police force—when I say “police force,” of different

divisions within that building—to protect their employees and to protect that property.

And it happens that in at least five cities over the weekend where there were some demonstrations, that the police force, if they were needed, the local police force did it. The only place where Federal law enforcement had to intervene was in Portland. And if the Portland police were protecting the Federal building, the people—the Federal employees there—would not have to do it.

I am going to introduce Soraya Correa—

Senator WYDEN. Mr. Chairman? Mr. Chairman—

The CHAIRMAN. I do not—I—you had your chance to speak about the damage in Portland. I just wanted to say what the situation was in Des Moines or other cities where they had the same problem.

Senator WYDEN. Mr. Chairman, could I respond for 1 minute?

The CHAIRMAN. Yes. Go ahead, please.

Senator WYDEN. Thank you, Mr. Chairman.

And let us just be clear. What we are concerned about in Portland, for example, is the attacks against our people even away from Federal buildings, one.

Two, overwhelmingly Oregonians are peacefully protesting, exercising their First Amendment rights. And I will just sum up with something I think you would identify with, and the Republicans would.

Tom Ridge, a Republican, the first Secretary of Homeland Security, said point-blank, hell would freeze over before he would have allowed something like this in his State.

Thank you for letting me make that clarification.

The CHAIRMAN. I will not comment on what you said, but I do have a reaction to what I see on television in Portland. When people set fire before the building, why isn't the fire department out there putting the fire out?

I am going to introduce Soraya Correa. She is Chief Procurement Officer for the Department. In her role, Ms. Correa oversees the work of nine heads of contracting agencies and their activities—well, I should not say nine agencies, but the activity of nine heads—that provide operational procurement services to the Department's Components, Directorates, and offices. She has initiated and led several key efforts designed to improve how the 1,400 members of the DHS Procurement Workforce focus as a team on finding the right solutions to enable and support DHS's mission.

This effort includes the Acquisition Innovations in Motion framework; the Procurement Innovation Lab; and the Education, Development, Growth, and Excellence mentoring program.

Thomas Overacker is the Chief Director of the Cargo and Conveyance Systems Office of Field Operations for the U.S. Customs and Border Protection. In this role, he provides leadership for all aspects of CBP's cargo processing and trade operations at ports of entry and Centers of Excellence and Expertise.

He oversees non-intrusive inspection and radiation detection technology for the agency, policies and procedures for cargo verification and cargo control, and trade compliance. He also directs the Customs-Trade Partnership Against Terrorism and the Container Security Initiative.

Steve Francis is Assistant Director for Global Trade Investigations at the U.S. Immigration and Customs Enforcement, Homeland Security Investigations, and the Director of the National Intellectual Property Rights Coordination Center. In this dual role, Mr. Francis oversees HSI's national program related to trade enforcement, intellectual property, and counter-proliferation. He brings more than 2 decades of law enforcement experience to that role. He served as special agent in charge of HSI's operations in Michigan and Ohio.

We will start as I introduced you, so go ahead, Ms. Correa.

STATEMENT OF SORAYA CORREA, CHIEF PROCUREMENT OFFICER, DEPARTMENT OF HOMELAND SECURITY, WASHINGTON, DC

Ms. CORREA. Chairman Grassley, Ranking Member Wyden, and distinguished members of the committee, thank you for the opportunity to appear before you today to discuss how procurement enables supply chain integrity in the U.S. Department of Homeland Security.

I am Soraya Correa, the Department's Chief Procurement Officer. I have been a career civil servant for more than 39 years and served at DHS since its inception. I oversee the work of 10 contracting organizations that provide operational procurement services to DHS Components, Directorates, organizations, and offices across the country.

My office manages the Department's procurement policy and processes and provides enterprise-level tools and contract vehicles. At DHS, we are accustomed to providing emergency contracting support while enabling the integrity of the supply chain—oftentimes during concurrent disasters and emergencies. We recognize the importance of ensuring contracts are awarded only to those contractors who are deemed responsible in accordance with the Federal Acquisition Regulations, regardless of operational tempo.

Immediately after the President declared a national emergency for COVID-19, my goals were to reduce any unnecessary administrative burdens to enable quicker delivery of supplies and services, to ensure employees and contractors had the processes and tools in place to carry out their work virtually, and to provide support to the DHS contracting activities in their work to research and vet vendors. To achieve these goals, I took several distinct actions early on.

First, I invoked the special emergency contracting authorities under the Federal Acquisition Regulations. For example, I increased the purchase card limit so that FEMA and others could more easily procure larger volumes of emergency supplies.

Second, I enhanced my communications framework with industry, contracting staff, and other stakeholders to share critical information on a regular basis. These forums focused on key areas of our work to support the pandemic, such as the CARES Act implementation, supply chain gaps, and how industry could better support the DHS operational requirements.

And lastly, in response to an extraordinary surge in inquiries from industry, I established two teams, a Supplier Verification Team that focuses on vetting potential suppliers for commercial

items, and the Procurement and Acquisition Innovation Response Team that focuses on innovative solutions.

These teams share the results of their work across DHS on a regular basis. Furthermore, they give industry a centralized approach to engage with DHS on COVID-19 and ensure that our Components and contracting activities are not duplicating efforts.

The activities I just outlined above, as well as others, serve as an underpinning for the collaboration with other DHS offices that is necessary to efficiently bring crucial solutions to bear through our operational contracting work.

In addition, FEMA used an open solicitation covering a broad array of items that immediately alerted industry to all of the COVID-19, PPE, and other related emergency response needs. The solicitation allowed FEMA to review responses and award contracts in an expedited manner to responsible vendors at fair and reasonable prices.

Finally, using the DHS Commercial Solutions Opening Pilot Program Authority, we issued a solicitation that remains open through August to obtain proposals for innovative commercial products that may help meet our new and emerging mission needs that have resulted from the COVID-19 pandemic.

In closing, I want to reaffirm my commitment to ensuring the Department has the products and services needed to fulfill its critical mission to safeguard the American people, our homeland, and our values. I continue to look for every opportunity to increase the efficiency and effectiveness of our policies and processes which help to ensure the integrity of the supply chain throughout the procurement process.

Thank you again for the opportunity to testify today, and I look forward to your questions.

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

The CHAIRMAN. Thank you.

Mr. Overacker?

STATEMENT OF THOMAS F. OVERACKER, EXECUTIVE DIRECTOR, CARGO AND CONVEYANCE SECURITY, CUSTOMS AND BORDER PROTECTION, DEPARTMENT OF HOMELAND SECURITY, WASHINGTON, DC

Mr. OVERACKER. Chairman Grassley, Ranking Member Wyden, members of the committee, I am Tom Overacker. It is my honor to represent U.S. Customs and Border Protection and to discuss what CBP is doing to ensure the integrity of the medical supply chain during the COVID-19 pandemic.

CBP serves on the front lines supporting the U.S. response to the pandemic, effectively managing trade and travel and mitigating risk. We are working to expedite the import of legitimate medical supplies and personal protective equipment, PPE.

CBP's dedicated personnel are on the lookout for counterfeit, substandard, or unapproved COVID-related products. CBP has prioritized communication with parties involved in the global medical supply chain. We work with the Food and Drug Administration, the Federal Emergency Management Agency, the trade community, and other stakeholders to ensure critical supplies reach their intended destinations here in the United States.

During fiscal year 2019, CBP processed 35.5 million entries valued at over \$2.7 trillion. Over the last 6 months, and as a direct result of the global pandemic, we have seen a 12-percent decline in the overall volume and a 13-percent decline in the value of imports. These declines reached their peak in May when the volume and value of imports were nearly 30 percent lower than May of last year.

Despite declines in overall imports, imports of medical supplies, especially PPE, have skyrocketed. In April alone, import quantities of these commodities increased by 227 percent. The number of new actors in the supply chain has also dramatically increased. The number of sellers of surgical and medical gloves has increased by 128 percent. The number of consignees acquiring protective masks has increased by 160 percent.

To segment risk and facilitate legitimate imports of medical supplies, CBP's Pharmaceuticals, Health, and Chemicals Center of Excellence and Expertise created the COVID-19 Cargo Resolution Team, or CCRT. The CCRT created an online portal to triage inquiries and provide up-to-date guidance from CBP and links to guidance from FDA. To date, the portal has received more than 21,000 views, and the CCRT has fielded approximately 2,500 inquiries, resolving cargo holds and expediting release of critical imports.

The efforts of the CCRT have helped secure the importation of approximately \$1.2 billion in COVID-related supplies. In addition, the CCRT worked closely with FEMA to support Project Air Bridge and other FEMA procurements. CBP successfully expedited clearance of over 400 flights at 17 different ports, facilitating the importation of over 1.3 billion pieces of PPE.

The CCRT is also engaged with the Department of Health and Human Services, supporting Operation Warp Speed to ensure that imports of critical equipment and supplies are not delayed.

In addition to facilitating legitimate imports, CBP is actively engaged in specific enforcement efforts. CBP collaborates with FEMA to ensure that scarce and threatened PPE remains in the United States for domestic use. CPB officers identify and examine export shipments and provide relevant information to FEMA for review and adjudication.

Together, FEMA and CBP have returned 3.6 million protective masks and nearly 150,000 sets of gloves to the U.S. market. Through CBP's National Targeting Center, we work with Homeland Security Investigations, the United States Postal Inspection Service, FDA, HHS, and numerous other domestic and international partners to identify and disrupt illicit imports.

NTC targeting efforts have led to the interdiction of more than 120,000 non-FDA-approved test kits, seizures of more than 10 million counterfeit masks, seizures of over 3,000 EPA-prohibited anti-virus lanyards, and interception of more than 20,000 tablets of medicines that were not approved by FDA for use in the United States.

The NTC directly supports Operation Stolen Promise, the HSI initiative to disrupt criminal organizations, the malicious cyber actors who prey on the public during the pandemic. The NTC provides rapid, real-time targeting support for HSI investigations.

CBP's officers, specialists, and agents remain committed to carrying out their mission, despite the personal health risks that they face in doing so. In these challenging times, CBP continues to protect the American people, safeguard our borders, and enhance the Nation's economic prosperity.

Thank you for the opportunity to testify. I look forward to your questions.

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

The CHAIRMAN. Thank you. Mr. Francis?

STATEMENT OF STEVE FRANCIS, ASSISTANT DIRECTOR, GLOBAL TRADE INVESTIGATIONS DIVISION; AND DIRECTOR, NATIONAL INTELLECTUAL PROPERTY RIGHTS COORDINATION CENTER, IMMIGRATION AND CUSTOMS ENFORCEMENT, DEPARTMENT OF HOMELAND SECURITY, WASHINGTON, DC

Mr. FRANCIS. Good morning, Chairman Grassley, Ranking Member Wyden, and distinguished members of the committee. Thank you for the opportunity to testify before the committee on U.S. Immigration and Customs Enforcement Homeland Security Investigations' response to those exploiting the COVID-19 pandemic.

Despite the widespread illness and death caused by COVID-19, individuals and criminal organizations operating around the globe are actively seeking to exploit the pandemic for illicit financial gain. The illicit schemes these entities employ compromise legitimate trade and financial systems, threaten the integrity of the U.S. border, and endanger the safety and security of the American public.

In my current capacity as the Director of the HSI-led National Intellectual Property Rights Coordination Center, HSI has been and continues to be well-positioned to leverage our resources and trust that have been built over the past decade among the private and public sectors to combat and investigate the illegal importation of harmful and counterfeit goods entering the U.S. supply chain.

When the pandemic struck, HSI saw the magnitude and potential threat of the pandemic to the American public and launched Operation Stolen Promise in April of 2020, a global strategy that utilizes HSI's unique investigative border authorities while leveraging our global trade and financial crimes expertise, robust cyber capabilities, and international global footprint to protect the homeland from the increasing and evolving threat posed by the COVID-19-related fraud and criminal activities.

Since the launch of this operation, HSI has opened over 570 criminal investigations worldwide, seized over \$7 million in illicit proceeds, made 53 arrests, executed 75 search warrants, and analyzed over 50,000 COVID-19-related domain names. And, while working alongside U.S. Customs and Border Protection, we have seized over 900 shipments of mislabeled, fraudulent, unauthorized, or prohibited COVID-19 test kits, treatment kits, homeopathic remedies, purported anti-viral products, and personal protective equipment.

Operation Stolen Promise was built around four central pillars: partnerships, investigations, disruptions, and education, each of

which represents a core element to addressing COVID-19-related crimes.

Since the operation's inception, HSI has implemented key actions under each of these pillars to take a comprehensive, multi-phased approach to combating COVID-19-related fraud across multiple fronts. HSI works alongside CBP on a daily basis to identify and investigate the illegal importation and exportation of these prohibited pharmaceuticals and medical supplies.

HSI's investigative efforts pursuant to Operation Stolen Promise have revealed that the degree of fraud is representative of the panic resultant from the pandemic. As information on potential cures, tests, and PPE requirements spreads through the public, the type of frauds quickly change to meet the perceived new needs.

For example, when hydroxychloroquine was touted as a potential cure, HSI saw a significant number of seizures related to this drug. Consumers have no way to know if these items are in fact legitimate, or if they will work if ordered from third-party marketplaces or non-medical websites. Many of the items obtained by CBP and HSI have not been approved by the FDA or EPA. Based on the seizures made in conjunction with HSI's partners and CBP, approximately 56 percent of our seizures originate in China and Hong Kong.

However, the COVID-19-related seizures also include 39 other countries that have exported prohibited goods. The largest percentage of seizures have been the COVID-19 test kits at 45 percent, followed by pharmaceuticals at 27 percent, viral lanyards at 16 percent, and PPE at 10 percent. While all the products are not necessarily counterfeit, they do not meet the U.S. regulatory standards and do not provide the medical benefits they claim.

HSI financial crimes units are working very closely with all our international, Federal, State, and local law enforcement agencies to initiate and pursue and support HSI investigations related to COVID-19 fraud. HSI has seen that the scammers have attempted to profit from the pandemic through a number of means, including bank, loan, and unemployment fraud; hoarding and price gouging; various medical scams; and online sales of counterfeit medicines, medical supplies, testing kits, and PPE.

Additionally, HSI has directed agents to pursue criminals who are engaged in crimes of victimization, with a particular focus on those who exploit the vulnerable populations, including the elderly.

HSI's work through Operation Stolen Promise has yielded tremendous statistical results in just a matter of months. These actions have kept prohibited pharmaceuticals, testing kits, and medical supplies out of the hands of American consumers; have prevented Americans from being victimized by financial scams; and have helped secure the integrity of the U.S. financial and trade systems.

Despite being faced with an unprecedented global health crisis, the men and women of HSI remain dedicated to carrying out this important mission.

I thank you for the opportunity to testify today and am happy to answer any questions you may have. Thank you.

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

The CHAIRMAN. Thank you. And before I use my 5 minutes, I am going to ask everybody to be really tight, because we have almost everybody on the list who wants to ask questions, and we do have two votes. And I am hoping for some cooperation from Republicans who want to ask questions so I can go vote and keep the meeting going while I go vote.

Ms. Correa, minority-owned small businesses have been disproportionately impacted by the virus. You are Chief Procurement Officer. You are in charge of vetting, reviewing, and coordinating incoming inquiries from the business community, and of course it is imperative that our government come together to ensure that business survives in the current circumstances.

Question one—and I only have two questions on this subject—how is your office prioritizing small businesses, including minority, women-owned, veteran-owned, that seek to provide aid and support to the Federal Government in responding to the COVID-19 pandemic?

Ms. CORREA. Sir, thank you for your question.

First of all, we at the Department of Homeland Security have a very robust small business program. We focus on small businesses. We do focus on prioritizing them in accordance with the Federal Acquisition Regulation.

When we think about small business, we think about first, what are the small businesses that are out there that could support us, and what categories are they in? And, how can we enhance their ability to participate in our solicitations and in our contracts?

In fact, the Department of Homeland Security has a very strong record with the Small Business Administration. We have scored a grade of “A” 10 years in a row because we meet or exceed each of the goals for each of the socioeconomic programs. So, we welcome small businesses. I personally meet with them, and we have a very robust small business program that reaches out to small businesses and helps them understand how to work with the Department.

The CHAIRMAN. I, just as a follow-up—this is not really my second question—but I asked about prioritization. Or are you able to take care of everybody? So when I talk about minority, or women-owned, or veteran-owned, they are taken care of? You do not have to really prioritize? Is that right?

Ms. CORREA. That is correct, sir.

The CHAIRMAN. Okay. Then the second question: how do we obtain innovative solutions to quickly solve future disasters or emergencies, from the procurement perspective? Is there anything Congress can do to help with the procurement process to ensure that we take advantage of innovative solutions?

Ms. CORREA. Senator, thank you very much for that question. First of all, how we obtain innovative solutions is, we actually put out a solicitation using our Commercial Solutions Opening Pilot Program to invite industry to identify solutions that might be commercially available that we might be able to use to address, whether it is alternative PPE or other supplies or services that would help us in addressing COVID-19.

We vet those solutions through the appropriate program officials, working with my colleagues here at the table as well as others

across the Department, to make sure that we are getting good solutions.

The second thing, the second part of your question, is how you might be able to help us. That CSOPP authority, Commercial Solutions Opening Pilot Program, is a temporary authority that is scheduled to expire in 2022. We would love to see that become permanent, because we believe it helps us find new solutions.

In addition to that, we have Other Transaction authority. That Other Transaction authority is typically used when we are doing research and development of new products. That authority expires on 30 September of this year, 2020. We would like to see that authority made permanent, as opposed to being renewed each year, so that we can proceed with many of the programs that we have to develop new solutions.

In addition to that, I mentioned the CARES Act, and it is very important. Section 3610 of the CARES Act was to enable businesses to maintain a ready workforce during this pandemic. So, businesses that perhaps could not telework might have to send their employees home. We want to make sure that we can protect their ability to maintain that workforce.

Unfortunately, in section 3610, what happens is, for fee-funded organizations, it is a little bit difficult to implement that solution. So creating greater flexibility in section 3610 of the CARES Act would be extremely helpful, sir. Thank you.

The CHAIRMAN. Mr. Overacker, I have, previously in my opening statement, talked about the study that we conducted. We found, in the report we put out, that certain legal barriers prevent your organization from sharing packing information. We also learned that this information could help identify high-volume sellers.

So earlier this year, CPB indicated its intent to create a procedure for disclosure of information otherwise protected by the Trade Secrets Act, which would address this very issue. Can you tell us the status of rulemaking? And are you working with stakeholders during this process? And I am going to have to stop with that question. Go ahead and answer it, and then we will go on to the next person.

Mr. OVERACKER. Yes, Senator, we are working on procedures that would allow us to disclose seizure data in a larger fashion, so that, whether it is the express carriers or any actors in the supply chain, they have a better understanding of who the violators are.

We are also working on something called "suspension and debarment," where we will actually suspend egregious violators from doing business with Customs and Border Protection.

The CHAIRMAN. I will submit one more question for you to answer in writing, and one question for Mr. Francis to answer in writing, because we are not going to be able to have a second round today. So if you would answer those, I would appreciate it.

[The questions appear in the appendix.]

The CHAIRMAN. Now I go to Senator Wyden.

Senator WYDEN. Thank you very much, Mr. Chairman. And, Ms. Correa, I am trying to see if you are out there. Can you hear me?

The CHAIRMAN. She is out there.

Senator WYDEN. Very good. So you are the Chief Procurement Officer for Homeland Security. And of course today we are looking

at the issue of defective and counterfeit COVID-19 medical supplies coming into the country. This is greatly important to my State. We bought respirators for health-care providers that could not be used because they did not meet quality standards.

And a major reason why Oregon's and other States' medical providers had to purchase these medical supplies in the first place is because the Trump administration walked away from its responsibility for organizing a national effort for procurement and distribution. My view is, forcing Americans to fend for themselves in a global market in the middle of a pandemic is not a remedy, it is a prescription for a mess, for a real health-care disaster.

Now, because you are the Chief Procurement Officer for Homeland Security, one of the primary Federal agencies that has responsibility to deal with these kinds of emergencies, I would like to know if you believe forcing State health departments, hospital systems, and doctors' offices to procure medical supplies from any source they could get their hands on was a sound national strategy?

Ms. CORREA. Sir, it is difficult for me to comment on that because I am not involved in that decision-making level. My focus is, as soon as requirements are identified to our Department to accomplish an acquisition, to make sure that we go out, secure those sources from responsible vendors, and ensure that we vet those vendors to make sure that we are getting the right product delivered to the right place at the right time.

Senator WYDEN. Respectfully, ma'am, I am not asking you about the politics. I am asking you about public health and public health consequences. The President said, and he said it point blank, acquiring PPE—he described it this way: “Governors are supposed to be doing it.”

My view is, that exposed States to serious health-care problems. It exposed the States to scammers on PPE. It forced them to compete against each other, rather than having the benefit—from a health standpoint—of a national plan.

So I would like you to tell me—set aside the politics—how forcing all of these health officials at the local level to compete to get scarce medical supplies in the absence of a national plan is sound public health policy. This is about public health, nothing else.

Ms. CORREA. Sir, but I am not the appropriate person to discuss public health policy. My responsibility is the procurement function.

Senator WYDEN. But from the standpoint of procurement, we are talking today about the health consequences of buying defective products. Let us talk about it just from a procurement process—the procurement process alone.

How is it in the interest of the American people for the States to compete against each other, to have all the scamming, and to have the problems we have seen? How is that procurement policy in the interests of the country?

Ms. CORREA. Sir, again, I am dealing with the Federal procurement process. We share information—

Senator WYDEN. I understand about that, ma'am. I am asking about a procurement process that is a prescription for a mess because we are walking away from our Federal responsibilities. And your title is Chief Procurement Officer. It is not Chief Procurement

Officer to try to figure out what to do if there is a flawed policy; it is Chief Procurement Officer to make sure that Americans in the time of a pandemic are going to be safe.

And I will just ask one other question. And that is, you heard me talk about the Department's focus on attacking my hometown and other cities, rather than attacking the coronavirus. How has the Department's effort with respect to the pandemic benefited by leadership, attention, resources, and efforts being focused on the streets of my hometown, the constitutional rights of Americans? How do we benefit from the standpoint of fighting the pandemic by deflecting Homeland Security's efforts in the way I described?

Ms. CORREA. Senator, I apologize, but I am not the right person to answer that question. Those are not policy decisions that I make. So, I apologize that I cannot give you an answer to that question, but I certainly will take that back to the Department so that it can be properly addressed.

Senator WYDEN. My time has expired, but just, Mr. Chairman, what this witness is doing is saying that procurement policy really does not have anything to do with public health. I think that is dead wrong, and that is the reason you are having the hearing, to try to make the case that somehow Americans are suffering primarily because of China from a public health standpoint. The reason Americans are suffering is because Donald Trump refuses to exercise national leadership with respect to this pandemic.

Thank you.

The CHAIRMAN. Senator Portman?

Senator PORTMAN. Mr. Chairman?

The CHAIRMAN. Yes. And before you go, Senator Portman, would every staff member of Republican and Democrat, if your member is not going to come to ask questions or do it virtually, I would like to know it, because we have a long list, and we have two votes, and I want to make sure we proceed expeditiously.

Senator Portman?

Senator PORTMAN. Mr. Chairman, the topic of this hearing is protecting the reliability of the U.S. medical supply chains, and I would like to focus on that issue. And it seems to me that the most important thing we can do to improve the reliability of our supply and deal with the fraud and counterfeits that we talked about earlier today is to reshore it, to have it here in America. And I think we have kind of missed that point so far in the discussion, and I think that should be our goal as Republicans and Democrats: to figure out how to have a truly reliable source going forward.

I think, secondarily, we ought to try to bring it at least to this hemisphere, because I know for some of the PPE, including gowns and masks and gloves, there is a concern about having adequate U.S. supply over the short term. But in conjunction with Mexico in particular, and others in this hemisphere, we have the ability to do that.

So my hope is that applying the very amendment which I think all of us have voted on one way or the other, but is law of the land, to say that we use domestic supplies and then, when we cannot, to use our hemispheric partners as well, ought to be our focus.

Since the start of the pandemic, I have been working with domestic industry in Ohio, and actually around the country, to figure

out, how do you reshore this stuff? You know, how are we going to get the PPE back here to this country, some of which frankly was never made in large volumes here in this country. And so we need to work particularly hard.

But the industry experts tell me every time that the best way to accomplish that goal is to provide some certainty. Provide some market signals, as they say, so they know if they make a big investment—and many of these versions of these factories and new factories are going to require big investments—that they will have a market. And of course the Federal Government is the buyer here.

And so I have been frustrated because we have not been able to get our own government, the Joint Acquisition Task Force, as well as now the DLA, Defense Logistics Agency, to send those signals, because they are not using long-term contracts for PPE. Instead, they are insisting on shorter-term contracts.

Right now, as an example for the PPE that we are talking about, typically it is a 90-day contract. So I guess my frustration is, if we really want to bring it back, there is a pretty simple way to do it, which is to say, “Look, here is a long-term contract. This should be enough certainty to be able to make the investment, and we can get moving on this.”

Again, this should not be a partisan issue.

Ms. Correa, you are an expert on procurement and I appreciate that, and I know that is your role. Can you help us understand why it is important for the government to send that strong demand signal to industry, and how long-term contracts send that demand signal and provide certainty for those seeking to invest in U.S. production, who work to bring this production back to our shores?

Ms. CORREA. Yes, sir. Thank you, Senator, for the question. Yes, the more information that we can give industry up front, and the better projections that we can give them of what we think we may need and when we think we may need it, and how much we are going to be willing to invest in that, the better they are equipped to respond to that.

Industries will turn. Companies will form. Large companies will partner with smaller companies, and there are mentor protégé programs in many aspects that enable companies to get into the business. But we have to do that with some level of certainty, and that means that we have to know what we need, when we think we are going to need it, and we are also going to have to know if we are going to have funding for that.

So that is extremely important. That is what industry wants to know and understand. I engage with industry quite a bit to find out what their needs are, what kind of information they are looking for, and that is the kind of information that they seek. And they are going to be willing to invest as long as they know that there is a long-term need.

Senator PORTMAN. Well, I thank you for that answer, and I think you are absolutely right. And part of it is back on us, because you are saying that not only do we need to have a requirement that there be long-term contracts—and by the way, we have legislation we are about to introduce that would require the Joint Acquisition Task Force, DLA, and others to use these longer-term contracts. But secondly, you need to know there is going to be a certainty of

funding so that the industries can make these substantial investments. And I look forward to working with you and others on this. Again, we hope to introduce this legislation shortly.

Let me talk about something else, which is the hospitals in Ohio, and I know around the country, that back in March and April were just desperate to find PPE. And frankly, they made a lot of contracts with companies, some of which were not traditional, but unconventional distributors that did not pan out.

Sometimes what would happen, I am told by Ohio hospitals, is one distributor would take orders from many hospitals and then, once the material was on its way over here, they would start the bidding process. And basically they would sell it to the highest bidder.

That was not the idea. Others, as you know, had problems with regard to counterfeits and outright fraud, in the sense that they were not delivering what they said they would.

Mr. Francis, these bad actors in our supply chain are now at the center of this investigation that you talked about. You said you had—in your testimony, I heard you had seized 900 shipments or more, Operation Stolen Promise. And I am glad you are doing that. I think it is important to investigate these, and we need to be identifying these bad actors right away.

But we also need to figure out how to prevent these types of situations from happening in the future. Because sadly, we are not out of the woods yet in terms of the coronavirus pandemic. And of course we want to be prepared for the next possible pandemic.

So can you help us on this? Again, obviously the best thing is to have a domestic supplier right here to avoid these kind of bad actors. But apart from that, what can we do to assure this does not happen into the future?

The CHAIRMAN. I hope you can give a short answer.

Mr. FRANCIS. Sir, one of the important pillars within Operation Stolen Promise is education. So we have a very robust private/public-sector partnership educating the consumers, educating businesses. We are working closely. We have done several public announcements, including the entire supply chain with Pfizer, Merck, 3M, Alibaba, Amazon, and Citibank in educating the American consumers about these fraudulent activities.

The CHAIRMAN. Senator Stabenow?

Senator STABENOW. Well, thank you very much, Mr. Chairman. And I want to echo the frustration that my friend Senator Portman just talked about in terms of not having the kinds of equipment, PPE, the things that we need here to deal with the medical pandemic in the United States.

I would say, though, it all comes down to not having a national strategy. We do not have a national strategy. We could. The Defense Production Act is something that has been used in the past, and certainly Michigan, which was called the arsenal of democracy in World War II, stepped up at the request of the President of the United States on behalf of our country during another kind of war.

So I think we are kind of skirting around the fact that we do not have a national strategy that would bring these products and the making of them to the United States, which is pretty straightforward and actually can be done here in the United States. And

I certainly support doing that, instead of pitting States and hospitals and everybody against each other. And unfortunately in Michigan, I have had to step in and be deeply involved in trying to figure out what has been incredible chaos.

But I want to share—in addition to what we are talking about overseas, an integrity in the system is really important. I want to share a story about something that happened in Michigan recently with a short-lived domestic company.

And, Ms. Correa, you have made it clear you are the Chief Procurement Officer. You oversee the contracting done by the Department of Homeland Security, including FEMA. And of course, you know, we have been working with FEMA and working with HHS to secure additional testing supplies for Michigan, as every other State has been pitted against each other.

But in June, Michigan received more than 322,000 tubes of COVID-testing transport mediums manufactured by a newly created company called Fillakit. Fillakit was incorporated 1 week before it was awarded the no-bid contract. It was headed by an untrustworthy individual who had been fined in the past for running telemarketing scams. And despite the concerns, FEMA awarded Fillakit, a company with no demonstrated ability to fulfill its terms, a no-bid contract for testing supplies. And so we subsequently found out that they were in fact using repurposed miniature plastic soda bottles. The reports were that the packaging process was unmasked employees using, quote, “snow shovels, dumping these things into plastic bins before squirting saline onto them, all in the open air.” They were not the appropriate size for the laboratory equipment. They were not manufactured in sterile conditions. And they would not provide reliable test results. And after our State lab raised deep concerns, FEMA and HHS told us not to use them.

So that is more than 300,000 tests we could not do, which is a week’s worth of tests in Michigan. So my question is—and I already wrote this to FEMA Administrator Gaynor and HHS Secretary Azar more than 4 weeks ago and have not gotten a response, so I will ask you. First of all, what are the criteria for giving no-bid contracts? And what steps were taken by FEMA during the contracting process to verify the accuracy of any representations or assurances made by Fillakit?

Ms. CORREA. Senator, thank you for your question. I am familiar with the Fillakit situation. I was made aware of it, and we have obviously notified and discontinued use of the Fillakit product. And we have referred the company for further investigation to the office of the Inspector General. And of course we are pursuing remedies under the contract.

To answer your question about what do we do, first of all, what you are referring to as a no-bid contract, we refer to it as a sole-source contract. That means we are entering into a contract with a single company. Often in these emergency situations, especially when we are buying commercial products, we rely on certifications or other authorizations from known bodies. In this case, Fillakit had an emergency use authorization provided by the Food and Drug Administration. We relied on that certification and entered into the contract and acquired these products.

We subsequently found out that those products were defective and, again, immediately notified the organizations that received these products.

Senator STABENOW. If I might just interrupt a second, so you are saying that FDA had approved this company that was put in place within a week of getting the contract, with all of the things that I described to you? They actually were certified by FDA?

Ms. CORREA. Yes. They had an emergency use authorization provided by the Federal Food and Drug—

Senator STABENOW. That is very important for us to know to follow up on. And I might say, in the interest of time, let me just go on to ask what controls do FEMA and HHS have in place to ensure that other entities that have been awarded contracts to provide COVID-19 testing supplies are in fact providing supplies fit for COVID-19 testing purposes? How do we know this is not going to happen again?

The CHAIRMAN. Please give a short answer.

Ms. CORREA. Yes. I cannot guarantee that it will not happen again, but we certainly include inspection and acceptance clauses in our contracts, and those clauses are based on the particular product that we are buying and how we are going to inspect and test the product.

The CHAIRMAN. Senator Menendez?

Senator MENENDEZ. Thank you, Mr. Chairman. The United States has passed 4 million COVID-19 cases recently. We know the growing number of cases is in part due to the rush to reopen in certain States without proper safeguards, and the failure to ensure mask wearing and social distancing.

And it is hard to comprehend that months after the virus's initial outbreak in the United States, we are seeing hot spots all over the country. And we continue to have the same problems procuring items like testing swabs and masks.

The reality is that we have had months to enhance our stockpile. We would not even be here and having this hearing if the administration had invoked the full power of the Defense Production Act, Federal purchasing, and coordination to ensure all of our communities had the basic materials to combat the virus.

Now flu season is about 2 months away, and I have severe doubts that we will be ready to deal with this ongoing pandemic during the annual flu cycle if real leadership does not emerge to coordinate our supply chain.

Now on July the 2nd, Rear Admiral John Polowczyk testified to the House Select Committee on the Coronavirus Crisis about the Federal Government's effort for procurement and distribution of critical medical equipment and supplies. He stated that the Supply Chain Stabilization Task Force is working through over 350 leads to match American businesses who have excess raw materials, workforce, or factory production capacities combined with a drive to support the national response effort. He also said Task Force members were working to facilitate partnerships to pair companies that offered their excess factory capacity, workforce, and access to their raw material supply chain with manufacturers who produce PPE and medical supply equipment.

So my question here, Ms. Correa, is would you agree that having a nationwide system that supplied an accurate and real-time capability and inventories could stop potential disruptions in the domestic supply chain and help the Task Force in their efforts?

Ms. CORREA. Sir, I am sorry. Could you repeat the question, because you kind of broke up a little bit? I apologize.

Senator MENENDEZ. Would you agree that having a nationwide system that could provide an accurate and real-time assessment of U.S. manufacturers' capabilities and inventories could minimize potential disruptions in the domestic supply chain and help the Task Force in their efforts?

Ms. CORREA. Sir, thank you for the question. Yes, in my professional capacity, I would agree that any time we have a system that enables us to more accurately vet and identify supplies, it certainly will always help.

Senator MENENDEZ. Thank you. And as the Chief Procurement Officer, would having a national view of the supply chain help us understand whether we need manufacturers to retool in key areas to meet the need of American products such as PPE and the medical supplies?

Ms. CORREA. Certainly, any time that we have insight into the capacities and the capabilities of our industry, certainly it will always make our purchasing processes much better and much more accurate.

Senator MENENDEZ. Well, I appreciate your response, because that is exactly why I filed a national supply chain database amendment to the National Defense Authorization Act and will be introducing stand-alone legislation which establishes a national chain database to the National Institute of Standards and Technology's Manufacturing Extension Partnership, which would give us that opportunity.

Let me ask Mr. Francis and Mr. Overacker. Even before the pandemic, we all knew that government agencies and the private sector needed to be doing more to stop the flow of counterfeit goods into our country. The rise of e-commerce has brought with it a flood of counterfeits and posed new challenges to our traditional ways of tackling this problem.

Mr. Francis, since the pandemic started, has the IPR Center worked with e-commerce platforms to encourage up-front screening of vendors, identified verification, or ways to more quickly remove counterfeit items from e-commerce sites?

Mr. FRANCIS. Thank you, Senator. We have been working with the e-commerce platforms since 2017 at least on some data-sharing pilot initiatives. Since the pandemic, we know there has been a significant increase in cooperation and collaboration as it relates to the data sharing in the marketplaces.

I am not certain about the pre-vetting. I know some marketplaces do a better job than others. However, I am optimistic. It is a voluntary-based data-sharing pilot program with the marketplaces, but I do believe that the pre-vetting with those marketplaces would definitely be beneficial in stopping these bad actors and organizations from exploiting the American public.

Senator MENENDEZ. And finally, would appropriating emergency funds to the IPR Center to tackle fake test kits, medicine, and PPE, be useful at this stage?

Mr. FRANCIS. Yes, sir, absolutely. Since the National IPR Center has been codified, there have not been any appropriated funds. Clearly it is a daunting task not only with the COVID-19 pandemic, but dealing with digital piracy, all these frauds and counterfeit goods that are entering the marketplace on a daily basis. Our priorities are national security, economic security, and the health and safety of the American public, and we would greatly appreciate appropriated funds. Thank you.

The CHAIRMAN. Senator Cassidy?

[No response.]

The CHAIRMAN. Okay; if Cassidy is not ready, then I go to Carper. Senator Carper?

[No response.]

The CHAIRMAN. Okay, then I will go to Senator Lankford. I am requesting that people who can ask questions let me know.

Senator Lankford?

Senator LANKFORD. Mr. Chairman, thank you very much.

Mr. Francis, let me ask you a little bit about the drug products issue that we have and the challenge of trying to get precursor chemicals in, and to be able to track how we handle supply chains for those particular chemicals that are coming in. What we need, where they are coming from, what we have—because there is a lot of conversation about pharmaceutical products and sales, but not the precursor chemicals before that.

So I want to ask you specifically about just the challenge of how to be able to determine what chemicals are needed, what precursors are needed, the locations; those are a problem. Obviously a lot of that is proprietary information as well. How are we doing tracking that?

Mr. FRANCIS. Sir, I am glad I have Mr. Overacker here next to me, but definitely it is very challenging. At the National IPR Center, we have a very robust initiative focused on the illicit precursors and chemicals and other products that come into the United States. We work very closely with the National Targeting Center investigations, where we have embedded special agents and analysts to really target those illicit goods from entering.

It is my understanding—and I have not received a briefing in a while—that many of these precursors were coming from China, and now we are seeing the evolution of these precursors going into Mexico and other countries and being smuggled across the Southwest border into the United States.

Mr. OVERACKER. And if I might add, Senator, with respect to legitimate importations of precursors by the domestic pharmaceutical industry in order for them to do their production, that is one of the reasons why, back in 2016 we created our Centers of Excellence and Expertise. Our Pharmaceuticals, Health, and Chemicals Center of Excellence and Expertise works very closely with the domestic pharmaceutical industry so that we have a keen understanding of what their supply chain needs are, and so that we can work with them to facilitate the legitimate importations of whatever precursor or production equipment they need to do their jobs.

Senator LANKFORD. Well, let me push back at that a little bit. Knowing where they are coming from is one thing. Actually having other alternatives and having a wider supply chain than having one or two countries that provide that, or pushing towards domestic production—

Is there an ongoing conversation about what is needed, where they are coming from, if we have an over-dependence on a particular country, in this case China, that we have all seen pretty clearly? The drugs may not come from China. The precursor chemicals are coming from China. To be able to know exactly how to be able to diversify that, what we are trying to actually get diversified?

Mr. OVERACKER. So, Senator, I would say the diversification of supply chain is critical to me, because we see right now the demand for products and the supply limitations that there are.

We do not pick the winners and losers in the supply chain, but we will work with the domestic pharmaceutical industry, the health-care industry, and other health providers in the United States to help ensure that we are not an impediment to the imports that they need to do their production.

Senator LANKFORD. Well, we can talk further offline at some point, because again I go back to—it is one thing to be able to know that we have a dependency in other areas; it is another thing to be able to know we have this dependency and we need to be able to diversify this to other countries and other places. Because having a supply chain map is good, it is a good start, but having an opportunity to say to companies, you are dependent on one place and that one place happens to be a communist country that we have already seen cut off supplies based on their needs rather than the needs of others—they will not fulfill contracts on a whim; they will actually just shut things off if they choose to, to be able to use economic pressure even if it causes the loss of life. That is not something that they care about in China.

So we have to be able to not only map where they are coming from but then develop the relationships to be able to press on those companies to say, “You need a more diverse portfolio, because you are putting American lives at risk by having a very narrow funnel for your suppliers.”

Has that kind of conversation occurred?

Mr. OVERACKER. No, those are not the conversations we directly have with the pharmaceutical industry at this time, but I understand your point, Senator, and I take it to heart.

Senator LANKFORD. Thank you. And that is one we will continue to have to be able to press back on some of those issues as well. We have also found this in the PPE and some of the products that are coming across.

There is some accusation that some of the PPE products that are coming into the United States from China and other places, that they are using forced labor for the production of those. Have we been able to determine one way or the other if forced labor is being used for production of some of the PPE coming into the United States?

Mr. OVERACKER. Yes. We have recently issued a withhold release order on nitrile gloves, which are medical standard gloves, coming

from Malaysia, for a particular manufacturer there where we determined that forced labor was being used.

So we continue to monitor these situations, and we act upon any leads or investigations that we encounter with respect to forced labor. Currently at CBP, I believe we have 13 active withhold release orders on products from a variety of countries, not just the nitrile gloves from Malaysia, but we continue to try to enforce our authorities with respect to forced labor.

Senator LANKFORD. Thank you. Thanks for doing that. Thanks, Mr. Chairman.

The CHAIRMAN. Senator Carper is next. I passed over Senator Cassidy, so if you will let me know that you are available, I will call on you after Senator Carper.

Senator CARPER. Thanks very much, Mr. Chairman. To our witnesses, welcome. There is a lot going on today, about six hearings that I could go to. I am sorry I could not get here sooner, but it is great to see all of you.

I have a couple of questions. I want to start off by talking—actually have you talk about the need for a whole-of-government PPE procurement strategy. And I would say this question will be for you, Ms. Correa.

We talked about the need to protect Americans by ensuring that PPE imported from other countries is legitimate. But counterfeits are only a small fraction of the problem, as you know.

Since March, I am told, there are hospitals, States, and local governments that have reported dire shortages of PPE, and I hear a rising again of those concerns. These shortages have become more acute in recent weeks as cases have shot up, likely contributing to the cycle of even greater demand.

As the Chief Procurement Officer at DHS, I assume it would be helpful to you to have a whole-of-government strategy designed to ensure availability of sufficient PPE, including from domestic sources. It seems the President could provide such a strategy in part by issuing orders to domestic manufacturers to produce PPE under the Defense Production Act. Do you agree that such a coordinated Federal strategy would help you to keep—and us, help us to keep costs down, and to ensure quality?

And the second half of that question would be, has DHS conveyed the need for such a strategy to the White House? And what has been the response? If you could handle those, I would appreciate it. Thank you. Again, welcome.

Ms. CORREA. Thank you, sir. Thank you for your question.

Certainly, a coordinated procurement strategy is always going to benefit. Any time that we can bring our sources, our resources together, identify the supplies that are needed, and engage our manufacturing entities out there to support that need, it is going to be beneficial to the government, to the State, local, and tribal organizations, and all the institutions that serve the public.

With respect to a communication of any such strategy or request for such a strategy, I do not have that information. I can certainly check with our officials at DHS who normally communicate with the White House.

Senator CARPER. All right; thank you.

My second question would be for you as well. It deals with sharing COVID-19 test results in public health IT. The pandemic, this pandemic, has exposed the cracks in our public health system, and in particular our antiquated public health IT infrastructure. In too many parts of our country, public health departments are relying on pen and paper. Their fax machines are old. Old software is used to collect and share COVID-19 test results. What are DHS and FEMA doing to help update and integrate public health data such as test results and demographic information in major transit points such as airports, train stations, and ports? What rules govern acquisition of innovative technologies? And how can we ensure that FEMA and DHS procurement officials have the necessary resources that they need to identify legitimate operators who can help bring our systems into the 21st century?

Ms. CORREA. Sir, I can only answer the question from the perspective of procurement. And as I mentioned earlier, we have several authorities that we want to use, and to continue using, to invite commercial innovative solutions that we can apply throughout our infrastructure—be it for supplies, services, or products.

I believe the appropriate officials probably to discuss the IT infrastructure with are really our Cybersecurity and Infrastructure Security Agency, as well as probably Health and Human Services. But I would certainly take that question back and get you additional information.

Senator CARPER. I will welcome that. A follow-up question to that one, if I can. One of the strengths of Taiwan's public health systems has, for example, been the country's ability to integrate demographic data from travelers with their public health system.

What is DHS doing with HHS and the CDC to ensure that domestic and international travelers' COVID-19 test results, or symptomatic information such as temperature checks, are quickly and accurately collected and shared?

Ms. CORREA. I am not the appropriate individual, because I do not work on the immigration data. I do not know if my colleagues—

Senator CARPER. Does anybody else want to try that?

Mr. OVERACKER. Senator, that is not my area of responsibility within CBP, but we are working with CDC and other agencies as we work on the plan of how we will monitor travelers that we process once we begin to receive more international travelers.

Right now, we are about at 5 percent of where we were last year at this time in terms of international travel. But I will take that question back and make sure that we get you the right answer on what CBP is doing with respect to monitoring travel.

Senator CARPER. Thanks so much.

Mr. Chairman, there is a company, actually a Delaware company that grew out of DuPont, that has been around for about 30 years, and they operate in I think about 90 countries around the world and a bunch of health-related companies in the U.S. Their name is LabWare—LabWare. And what they do—imagine, if you will, a small suitcase that has in it a tablet. That tablet would be used instead of pen and paper to take down the information from people who are about to be tested.

And they use their driver's license that actually has a bar code on the back of the driver's license, to bring down and to unite with the information from the tablet, who this is, what their background is, where they live, and everything. And they marry with that the test result. It could be a swab, it could be blood, or whatever, test results that go up on the cloud and are brought down and put in public health agencies across the country. It is really great stuff, and it helps make for more accurate information more quickly, and it is actually very helpful, I think, in terms of tracing and that sort of thing.

So I just raise that as American technology—LabWare.

The CHAIRMAN. Thank you, Senator Carper.

Now we go back to Senator Cassidy, and if Senator Cardin gets ready, he will be after Cassidy.

Senator CASSIDY. Thank you all.

First, I just want to put a plug in. We understand that online activity with counterfeit goods has been a major issue here. And so I have introduced two bills, one the SANTA Act regarding children's toys, and secondly the INFORM Consumers Act, which would ask online platforms to list, if it is a third-party seller, who is that seller, so that you can see their address. If they are selling a product, a 3M product, but it is not 3M, you would know that if that was the case.

So anyway, just to put a plug in, and of course we would love if folks support it as we go forward either from the committee or from outside of government. So let me ask—and I will let somebody decide who should answer this, but I gather that Chinese companies, or those from Hong Kong, are often involved with the online sales of counterfeit goods.

And so if—and I think that this COVID crisis has demonstrated the vulnerability of our country to having so many supply chains going through China. Could we potentially decrease the number of counterfeit goods flowing into our country if we were to move supply chains out of China into Mexico or Central America or someplace else? Or would the counterfeiters just move their operations?

Any thoughts on that?

Mr. FRANCIS. Senator, thank you for the question. You know, over the last 5 years, on average about 85 percent of our seizures related to counterfeit goods have come from China and Hong Kong. And that has been an issue to protecting the health and safety of the American public.

I think that with IP and counterfeits, or prohibited goods, that China and Hong Kong have been the places of origin for the goods that are coming in that are harming the American public, and also harming the U.S. economy.

So, yes, to answer your question, I believe that that could be a potential solution to reduce the number of counterfeits coming from those countries.

Senator CASSIDY. And you may have answered this earlier—I apologize if I missed it—but to what degree are those governments collaborating and cooperating with us? If we identify somebody as a counterfeit producer and/or shipper, are they in turn cracking down? Because certainly mainland China, and now Hong Kong, has a high level of government oversight.

So are they collaborating with us as we attempt to stop this 85 percent of the counterfeit goods coming from there?

Mr. FRANCIS. Sir, thank you. Homeland Security Investigations has an office in Beijing and also in Hong Kong, and we do receive tremendous support on our criminal investigative efforts. The Hong Kong and Chinese officials both support our investigative efforts, especially if it relates to health and safety products.

Senator CASSIDY. I am a little bit, though, confused. Because in a country in which there is such facial recognition, so if I walked into that country and flew around, there would be a camera taking pictures of my face wherever I went. So how much of this is a pro forma collaboration and how much of it is actually effective? Let me ask that first.

Mr. FRANCIS. Sir, it is difficult for me to answer that today. When we submit requests to our offices in Beijing and Hong Kong, working through our special agents there, we are receiving support and collaboration. I know that there is continuing, ongoing support from both areas.

I am not really sure if I can answer that question specifically.

Senator CASSIDY. Got it. Let me ask you this: what is the connection between counterfeiting and human and drug traffickers, or other illicit activities? I get a sense that we have a threat network, and that they are just on the one hand doing counterfeiting, and on the other hand they are doing illicit financing. And it seems like it is a whole web, if you will, of criminal activity. Is that a fair statement?

Mr. FRANCIS. It is, Senator, yes. It is intertwined. There is international money laundering. There are these transnational criminal organizations that are involved not only in trafficking of drugs, but human trafficking as well as IP crimes. As you can imagine, intellectual property theft is very profitable with minimal prosecutorial risks. So the profitability is what these organizations and bad actors are pursuing.

Senator CASSIDY. And so it has been my premise that we need an interagency task force that would work on this, because it is not just Customs but it is also illicit financing, and it is also—you know, name all the things—so we should have an interagency task force.

I cannot see the clock. I am assuming I am almost out of time, so if you could comment on that, Mr. Francis, and I will let that be my last question.

Mr. FRANCIS. Thank you, Senator. That is exactly why we launched Operation Stolen Promise in an effort to bring together our cyber capabilities, financial capabilities, intellectual property, our international operations. I really think the COVID-19 pandemic and the response that HSI has had with Stolen Promise will change the way we look at intellectual property theft, as well as the prohibited goods entering the United States.

The CHAIRMAN. Senator Cardin? And will Senator Brown be ready after Senator Cardin?

Senator CARDIN. Mr. Chairman, thank you very much. I appreciate all our witnesses and their testimony.

Maryland has had problems that we have seen in all States. We have had challenges on the supplies that we received, including the

supplies that we have received from the Federal Government, from FEMA. We have had real shortages in providing PPE to our health-care providers and to our nursing homes, and the list goes on and on and on.

Our Governor, Governor Hogan, has been pretty aggressive in trying to protect the supplies for the people of the State of Maryland, but it has been clear, as he has pointed out on numerous occasions, that the inconsistencies coming out of this administration on how the supply chain was being protected caused confusion among States, caused conflict among States, some misinformation. And today, we still have the challenges of an inadequate supply chain.

So I appreciate all the comments that have been made. We have received fraudulent goods also, and that is an area of major issue.

I want to ask my question though, if I might, in regard to the issues of hoarding and gouging, as to what effectively we are doing in order to prevent the hoarding and to take action against those who are doing price gouging to try to take advantage of this emergency situation.

Our States have acted with the State laws that deal with price gouging, and there is inconsistency between the approach taken by the Federal Government and our States.

Could you share with me—and I think this should probably go to Ms. Correa, or perhaps Mr. Overacker—who is the point person at the national level to try to coordinate the efforts of our States, and with those that have the claims against those companies that have been taking advantage of this public emergency?

Mr. OVERACKER. Thank you for the question, Senator. With respect to hoarding and gouging under the Defense Production Act, there are actors within the Federal Government, whether it is HHS, or FEMA, or the Department of Justice, who are currently pursuing investigations into the hoarding and gouging.

CBP's role primarily is to act upon appropriate allocation orders that we may receive, but also to work with those partners to identify imports that may or may not fall into that category. And we support investigations in that light.

With respect to who is the ultimate authority within the Federal Government on investigations for hoarding and gouging, you know, it is not CBP. We are not investigators. But I do know that the Department of Justice is heavily involved in these cases.

Senator CARDIN. Ms. Correa, would you like to add to that?

Ms. CORREA. Yes, I was just going to add that, yes, the Department of Justice would be the primary agency that acts on prosecuting these organizations. If we are aware of any information, or we obtain any information on any elements of price gouging or hoarding, we refer the matter to the Inspector General who does an investigation, and then the matter gets further referred to the Department of Justice.

Senator CARDIN. Could you just share with me how you are working with State law enforcement so that we have a united effort to deal with hoarding and gouging?

Mr. FRANCIS. So, Senator—this is Steve Francis—I would like to respond to that. As it relates to hoarding and price gouging, the U.S. Attorney's Office out of New Jersey is leading the Task Force

effort there. We do have significant HSI-led investigations on hoarding and price gouging, and we are working very closely with State and local officials.

So specifically with the investigation out of New York City, this was an individual who was hoarding and gouging PPE—face masks. We seized over 1.7 million, working alongside NYPD, CBP, as well as the Postal Inspection Service and the DEA.

There are a lot of efforts among the Department of Justice, not only with the Consumer Fraud Protection Branch, Hoarding and Price Gouging Task Force, but we work closely with the Computer Crime and Intellectual Property Section with DOJ.

So it is a tremendous whole-of-government effort relating to that, and we are working very, very closely with our State Attorney Generals' offices.

Senator CARDIN. Thank you, Mr. Chairman.

The CHAIRMAN. Okay. After Senator Brown gets done, for the benefit of our witnesses, I am going to have to, not adjourn but to recess this hearing, because I cannot get a single one of the Republicans to come over and chair while I am voting. And so you will just have to do whatever you do when we are in recess.

But be ready to come back quickly, because I will vote on the last vote—or I will be voting on the first vote last, and then I will be the first one to vote on the second vote, and then I will not be bothered anymore.

Senator Bennet, you will be up right after Senator Brown. Yes, yes. Bennet is right after Brown.

Senator Brown, take your 5 minutes.

[Pause.]

The CHAIRMAN. Senator Brown? If Senator Brown does not show up, you could—go ahead, Senator Bennet.

Senator BENNET. Thank you, Mr. Chairman, and I would be happy to—

The CHAIRMAN. Go ahead.

Senator BENNET. I would be happy to chair the hearing for you, if you would like.

The CHAIRMAN. I would—tell you what: you use your 5 minutes, and then recess it. And I will leave now—

Senator BROWN. Mr. Chairman, Senator Brown just got back. Could I go after Senator Bennet?

The CHAIRMAN. Yes, you can go after Senator Bennet, but it will be after our recess.

Senator BENNET. Why don't I yield to Senator Brown, and then—

Senator BROWN. No, no, I do not want to do that. Go ahead, Michael.

The CHAIRMAN. Go ahead.

Senator BENNET. Okay. Thank you to the witnesses for being here.

Ms. Correa, I wanted to reflect a little bit about what we have heard today from my colleagues, Republicans and Democrats, on what is going on in my State of Colorado, which is that we confronted massive shortages of PPE early on in this pandemic.

We are confronting massive shortages of testing equipment. The administration seems to believe that we have an issue with respect

to testing sites. That is not the issue. The issue is that our hospitals do not have access to the supplies they need to be able to test our citizens—by the way, unlike any other country. You know, many other countries in the world have access to testing supplies, and have access to testing that allows people to get a response in a day or less than a day.

In my State, it has now gone back to 7 days, 11 days. If you are living in a rural area, 12 or 13 days. And now that we are 5 or 6 months into this pandemic, what we have seen is, every single hospital in my state—and I would say in the United States of America—is in competition with one another for exactly the same supplies. The veterans hospital, the VA hospital in Denver, has no national plan that they are a part of. They are competing with every other hospital in America to get PPE for the people who work at the VA, to get testing supplies for the people whom they need to test.

And not surprisingly, what has happened is, we have seen the kind of nefarious behavior work its way into our supply chain which the other witnesses have testified to. That is a serious problem, and I am glad they are here to testify. But an equally serious problem, I would argue—and maybe an even more serious problem—is that we have massive shortages across the country. And the prices of things like masks and gowns and the booties that people have to wear, have all gone through the roof.

In Colorado, I think the estimate at Denver Health—you know, filled with people on the front line supporting one of our most important public hospitals—the price of masks has gone up 41 percent. Earlier on in the year it was up 100 percent.

So—and by the way, we are also competing with FEMA from time to time, because FEMA has come in occasionally and said, nope, we are going to take all the ventilators, or, nope, we are going to take all the masks. And I do not know where they are going, if they are going to Arizona, or Texas, or whatever.

So we have a completely broken system out there. And what I would ask you is this, Ms. Correa, and I ask you this in the spirit of somebody who respects the fact that you have worked in the Federal Government for, as you said, I think 39 years. If this committee came to you, or the administration came to you and described the situation that we are confronting—I think we can stipulate that what I am saying is accurate; it is consistent with what everybody here has said. If we came to your team and said, “Help us solve this problem of scarcity, of not sufficient testing, of prices that are going through the roof because of no coordination,” what would you tell us you could do if you had the authority to do it, either administratively or legislatively? What could your team of people, committed public servants, do to help America begin to act like we are a first-world country facing this pandemic?

Ms. CORREA. So, from a procurement perspective, from where I sit and the role that I play, yes, if somebody could identify for us what the need is, what the requirement is, where the fund sources, all those things are, then we could coordinate amongst our procurement organizations, whether it is the Joint Acquisition Task Force at the Department of Defense, Health and Human Services, Department of Homeland Security, VA, and other agencies, we could

coordinate so that we could identify what the sources of supply are, provided that those sources are out there, and how we might best fulfill that need.

So, yes, we could coordinate amongst the procurement organizations, but we would need to understand what the requirement is, what those sources—

Senator BENNET. And when you say you need to understand what the requirements are, do you think you have a—I mean, do you understand the requirements in the hospitals in Colorado? Do you understand the requirements of the—

Ms. CORREA. So, we do not get that data, personally. It comes through, in some cases, the folks who are coordinating with them, such as when FEMA was running the National Response and Recovery effort, they were coordinating and getting information in, and that is how we were—

Senator BENNET. Who is giving you that information now?

Ms. CORREA. Typically, it comes from States—well, I cannot answer that question right now, because right now the Joint Acquisition Task Force has taken over the purchase of PPE and non-PPE supplies on behalf of HHS because FEMA got freed up to support disasters and national emergencies that are coming up.

Senator BENNET. What disasters and national emergencies that are coming up?

Ms. CORREA. Like hurricanes—

Senator BENNET. So you have been taken off of COVID, then?

Ms. CORREA. FEMA is not leading that effort anymore, not the purchasing part. FEMA's National Response—

Senator BENNET. So here is what I would say, and I am going to adjourn for the chairman. You know, the President said, "I am not a shipping clerk." That is a point of view, I suppose. It is not a point of view that most Presidents would have had when faced with a global pandemic. I mean, a global pandemic, I would think, would be a moment where, at least for one moment, we are one Nation under God trying to solve the problems that we are confronting.

And not only did he say he is not a shipping clerk, he said, "I'm glad they're having this competition because it will create price discovery and the lowest prices will be available to people and hospitals across the country."

And as you know, Ms. Correa, the reverse is absolutely true. Which is that, when you have the kind of scarcity we are confronting, when you cannot predict whether the COVID virus is going to be in Arizona next week, or Texas the week after that, or Colorado the week after that, what we have seen is not price transparency but the kind of gouging, the kind of misbehavior, the kind of increases in prices that have made it even more difficult for us.

So I would say this has been a catastrophic failure on the part of President Trump. And I feel bad about it, in part because I know the quality of the people who work for you, and I know what they could do if they were given the opportunity to actually do what we need them to do. And I hope they will get that chance.

I will, in regard to what the Senator from Iowa said, now adjourn the hearing until he returns and calls on Senator Brown. Thank you. The meeting is adjourned.

[Whereupon, at 11:59 a.m., the committee recessed, reconvening at 12:28 p.m.]

The CHAIRMAN. I am told that Senator Casey is ready. Senator Casey? If Senator Casey isn't ready—

Senator CASEY. Yes, I am ready.

The CHAIRMAN. Oh; go ahead, Senator Casey.

Senator CASEY. Mr. Chairman, thank you very much. I had trouble with my microphone there.

Thank you very much. And I want to start with Ms. Correa regarding domestic production chains. But I wanted to say, first, that I realize that there are times when it is very important for us to hold accountable public officials, either appointed or elected. But sometimes you have to start with the elected official.

And when it comes to what I believe is a colossal failure on personal protective equipment, PPE, I think the failure started with the elected President and has gone down from there. And so a lot of my frustration that I have, and a lot of Americans have, is directed at the President's failure to take the virus seriously, to have an action plan, and to put himself and put the Nation on a war footing.

If you are a commander-in-chief and you've got a war against a virus, you have to act like it every day. And there should have been an all-out effort, call it what you will, Marshall Plan or something on that order on personal protective gear, and it never happened. It just never happened.

In *The New York Times* this weekend there was a major story headlined "FEMA Sends Faulty Protective Gear to Nursing Homes Battling Virus." Nursing homes? We are now very close to the 60,000 mark—60,000 dead in nursing homes. That means residents as well as workers in those nursing homes, and no strategy to get that number down. And a component part of the strategy is PPE, we know that.

You have to ask yourself, is this the United States of America? We cannot make enough masks and gloves and gowns? And I am not saying it is all the failure of one administration, but the recent failures, there is no question where the failure emanates.

Let me start with some testimony from last week. House Ways and Means Committee, Kim Glas, president and CEO, National Council of Textile Organizations—that's the Association of Domestic Textile and PPE producers—said, "The U.S. textile industry is only running at 10 to 30 percent, and many mills are idle."

Ms. Correa, I wanted to ask you, can you explain the PPE shortages? And why have we not maximized domestic—domestic—production?

Ms. CORREA. Sir, I probably should clarify my role as the DHS Chief Procurement Officer. I am part of the supply chain, and I am part of what helps create integrity in the supply chain, but I do not direct the manufacture of equipment. I identify requirements when they are known to us, get them out to industry, and hopefully get proposals back, or information back that we can use to award contracts.

So, it is hard for me to answer that question, because I am not the appropriate person to answer that question.

Senator CASEY. Well, it is a question that I think the administration should answer, even if—and I know you have been engaged in public service a long time for the Federal Government—but we need to get an answer to that kind of a question.

Can you answer this question about purchases that you have directed on behalf of the government? How much domestic PPE have you purchased versus foreign-manufactured PPE?

Ms. CORREA. So, I do not have the exact figures on that. Our first priority is to buy domestic product, in accordance with the Buy American Act, and when such product is not available, if U.S.-based companies do not have product, then we investigate to see what other product they have and where that product comes from.

Companies do have to disclose if they are providing a foreign product in response to a Federal Government solicitation. But I can get you the exact figures. I just do not have those with me right now.

Senator CASEY. Well, that would be very helpful, I think, for the committee to have a quantification of that number.

And finally, I wanted to ask you about the process by which you quantify the demand for the purchase of PPE. Tell us about that. Tell us what you can about that, what the demand is and how you proceed with that.

Ms. CORREA. Sure. Through our logistics coordinators, our program officials identify what the requirement is. What are the needs, where the products are needed. They bring that into the procurement organization, and then we accomplish the buy.

So, for example at FEMA, through the National Response Coordination Center, they work with State and local officials to identify the requirements, the type of equipment that they need, and then the purchasing organization does the buy.

And then typically, the shipments are made to a distribution center or location, and then they further distribute the equipment out to the appropriate organizations.

Senator CASEY. Okay. Well, in the final seconds I have, one of the real indictments in this article I mentioned was from a University of Chicago health economist who said, quote, “The Federal response to protecting one of the most vulnerable populations in this country [meaning nursing homes] has been a dismal failure,” unquote.

And that starts with the President. And beyond this pandemic, we need a whole new industrial policy in this country to produce enough PPE. The same country that put a man on the moon more than 50 years ago ought to be able to produce enough gowns and masks and other protective equipment. There is no way we should settle for this, especially in the context of nursing homes.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Hassan, if you are available.

Senator HASSAN. I am available, Mr. Chairman. Can you hear me?

The CHAIRMAN. Yes, I can hear you.

Senator HASSAN. Okay, great. Well, thank you, Chairman Grassley and Ranking Member Wyden, for holding this hearing, and to our witnesses for participating today.

The COVID-19 pandemic is increasing demand for medication, supplies, and personal protective equipment. And the medical supply chain is not keeping pace. And it is going to be exacerbated if we do in fact start to physically reopen schools moving forward. I was just on the phone yesterday with a number of my school districts in New Hampshire, and they are scrambling to find PPE.

In addition to being responsible for shoring up manufacturing and distribution capacity for things like masks and gowns, the Federal Government is responsible for ensuring that products in the medical supply chain are safe. This includes ensuring that counterfeit medical products do not enter our country's supply chain.

Last week, Senator Enzi and I introduced the Safeguarding of Therapeutics Act, which is bipartisan legislation that would give FDA authority to seize counterfeit medical products so they cannot reach patients and front-line health-care workers.

I hope my colleagues will join Senator Enzi and me in calling for this bill to be included in the next COVID-19 relief package.

I have a few questions, but before I ask those, Ms. Correa, I wanted to follow up on something you said in a couple of your answers so far, where you have indicated how important it is to you to have an understanding of what the demand or need for a particular product is. And I have not been able to tell from your testimony whether you in fact believe your office has the information about what the projected need for personal protective equipment is.

About a month ago in a hearing before the Homeland Security and Governmental Oversight Committee that I sit on, Director Gaynor from FEMA produced to the committee a chart of the need for various personal protective equipment month by month, and where we were in terms of supplying that need either domestically or from overseas.

And I just wonder if you have seen it? It is labeled "White House COVID-19 Supply Chain Task Force," and if you have not seen it, we are happy to get it to you. But I just wanted to understand whether there has been communication about that?

Ms. CORREA. There is communication about that. And perhaps I should clarify. It is not that we do not know the projected need. In the Procurement Office, what we do is actually accomplish the buy.

First of all, DHS right now, through FEMA, was supporting the COVID-19 response. The transition of the procurement function has now happened, and DLA is supporting the overarching buys, if you will, to support the pandemic response. FEMA is now focused more on the disasters from a procurement standpoint.

In the Procurement Organization, we take those projections. We will share them with industry. But for us to accomplish the buy, we not only have to have the projection but where we are going to ship these supplies, or who we are going to send them to, and the funding to accomplish the procurement so that we can award the contract.

Senator HASSAN. So what information—are you lacking information now about where you need to send them and what sectors have the greatest demand?

Ms. CORREA. As I indicated, the DLA is actually who is buying for the government-wide buy in response to the COVID-19 response now. But to answer your question, right now, no, I do not

have any requirements in front of me to buy, or funding to make the procurement happen.

DLA, like I said before—and the Joint Acquisition Task Force—is now taking over the procurement from a national response.

Senator HASSAN. Okay, I understand that. So I will ask, Mr. Chairman, without objection, for the slides that were produced last month to the HSGOC Committee, to be entered into the record.

The CHAIRMAN. Without objection, so ordered.

[The slides appear in the appendix beginning on p. 74.]

Senator HASSAN. Thank you. I do have another question for Mr. Overacker and Ms. Correa.

Since the onset of COVID-19, States and health-care facilities have been scrambling, and often competing in expensive bidding wars with each other, to get enough medical supplies to meet the needs of health-care workers, patients, and businesses.

At the same time, there are reports of an increase in the production and trafficking of counterfeit products. What specific medical products and supplies do you believe have been the focus of counterfeiters since the start of the pandemic? How is that impacting the safety of patients and health-care workers?

Mr. OVERACKER. So, with respect to how we deal with just the rapid increase in the number of people who are trying to obtain PPE supplies and facilitate legitimate imports, that is one of the primary reasons why we created our COVID-19 Cargo Resolution Team. They stand at the ready to assist new actors in the supply chain so they understand the importing requirements and what needs to take place in order for us to rapidly facilitate the legitimate imports.

With respect to illicit imports or counterfeits, from the very beginning of this crisis I think some of the first things we saw were counterfeit masks. And by counterfeit masks, I mean masks that would have a trademark on them for an actual known provider. But also, in addition to counterfeit masks, we are just seeing other illicit products such as—we mentioned this before—these what they call “shut-out lanyards,” which are basically a sham product that tells people if they wear this around their neck, it will protect them from COVID.

So these are the types of things that we have seen. How we try to combat this is, whenever we encounter these at our ports of entry, that is information, a data point, that we use to share with HSI so that we can begin investigations into the people who are trafficking. And then we use our targeting capabilities to support HSI’s investigation.

The CHAIRMAN. Before I call Senator Brown, I would like to know if four Senators—well, Senator Cantwell is here, so virtually, are Cortez Masto, Daines, and Whitehouse going to participate? Just let my staff know.

I go to Senator Brown now.

[Pause.]

The CHAIRMAN. Senator Brown?

Senator BROWN. Thank you, Mr. Chairman. I really appreciate it.

Before I begin my questions, I want to take a moment to express my outrage at the action of the Department of Homeland Security in cities across America. I echo the words of Senator Wyden, our

ranking member. It is unconscionable that in this country—in this country, in America in 2020—our President is treating our own cities like war zones, sending unidentified Federal forces, talking about “deployments,” as if Oregon, Illinois, and New Mexico are foreign battle fields.

These agents arrest our own citizens who are exercising First Amendment rights. They are standing against police brutality. They are standing in support of Black Lives Matter. The President has no problem trampling on the constitutional rights of Americans. None. We should be outraged by that.

So, Mr. Chairman, I would start with Ms. Correa. My first question is for you. I have been in touch with a number of Ohio and American manufacturers around the country who describe procurement processes—they call them “completely chaotic.” They get bounced around from official to official with no idea who is actually in charge. In fact, it is clear no one is in charge.

The procurement terms change repeatedly with no explanation. One urgent gown solicitation was canceled at the last minute because the government decided it needed a different type of hospital gown.

Do you think this lack of coordination has contributed to PPE shortages and delays, Ms. Correa?

Ms. CORREA. Sir, that is a difficult question for me to answer. Certainly, it could contribute to that, but I am not aware of those concerns with respect to DHS. We established the process for industry to be able to communicate with us. We centralized communications through an industry liaison mailbox. And then we had teams of people who were vetting any requests for information, whether the request was about an existing solicitation or about future work, or even how to do business with the Department.

Senator BROWN. Well, Ms. Correa, if I could, these requests—in some cases these requests were directly to the White House, directly to Mr. Navarro, whom the President designated to do this, and the chaos just continued.

All of this has unnecessarily exposed front-line workers to COVID-19. It has prevented them from producing the amount of tests we need to get kids back to school, to get workers back safely, kids back safely to school, workers back safely on the job. It seems clear to me that increasing domestic production of PPE would make us better-equipped to respond to future public health emergencies but almost completely resolve concerns of counterfeit face masks and other equipment.

Do you agree with that, yes or no?

Ms. CORREA. I believe that if we can increase production in the United States, certainly that would help our supply chain.

Senator BROWN. Thank you.

Mr. Overacker, my next question is for you. In 2016, the ranking member, Senator Wyden, and I closed a longstanding loophole that previously allowed certain imports made with forced labor to enter our country. Because of our amendment, U.S. law prohibits any products from entering our country made with forced labor.

I have read news reports about imported face masks made in China by Uyghurs, whom we know are subject to forced labor conditions by the Chinese Government.

Can you tell this committee with certainty that no PPE supplies that have been made with Uyghur forced labor are entering the U.S.?

Mr. OVERACKER. So, Senator, with respect to forced labor, that is one of the things we are looking at in that region of China where Uyghurs are, what products that are coming out of there. We do have active investigations underway.

We have already initiated at least one withhold release order, not pertaining to the masks but to other products from that region of China. And we continue to investigate that. We have also recently issued a withhold release order on nitrile gloves from Malaysia. But, Senator, we will go back, and I will make certain we get all of the information we have on what we are doing currently with respect to the region of China where the Uyghurs are located.

Senator BROWN. Thanks, Mr. Overacker. I appreciate your candor. The administration's answer to that question would be, "Yes, we are certain we are not importing Uyghur products." I mean, I know the President's uneasy relationship with the Uyghurs, that he does not generally stand with human rights groups and oppressed minorities in countries; he stands with the dictators at the top, whether it is President Xi, or the President of North Korea, or Turkey, or name the country.

But the law is the law. And I am hopeful, when I send a follow-up letter to you, that you can not just tell us the specific actions, but address how effective those specific actions are. Because it is the law.

Mr. Chairman, this pandemic has been the great revealer in so many ways in our country. It has revealed the racial disparities that are rampant in our health-care system and our economy. It revealed the President's lack of economic leadership. Supply chains are critical in a crisis like this one. We have all had individual cases in our States where we tried to get companies that could step up and produce PPE, and those companies say they have run into chaos or indifference at the White House.

So I am introducing, because of all this, because we must make domestic production a Federal priority, I am introducing the Protecting American Heroes Act tomorrow. My bill will increase U.S. production of PPE and other critical items in the Strategic National Stockpile and make sure we are better-prepared for a pandemic.

It will mean we will be better able to quickly increase production of the supplies we need in an emergency, made by Americans. I look forward to working with my colleagues on this committee to get it signed into law.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Cortez Masto, if you are available.

Senator CORTEZ MASTO. I am. Mr. Chairman, thank you so much for this hearing, and to the panelists, thank you for appearing today.

Let me start with Mr. Overacker. I am from Nevada. I have been working closely with my Governor's office, and I have learned from them that the CBP processing time has slowed the arrival of PPE in Nevada, so much so that they are also seeking to attain the guidance directly from China because the State's demand has surpassed the Strategic National Stockpile allocation.

But here is my concern. I am being told that once these shipments do arrive, they sit with CBP. The Governor's office and the FEMA regional administrator have been great to work with the State of Nevada in helping us shake loose those orders.

Mr. Overacker, you described the COVID-19 Cargo Resolution Team, whose work included coordinating with government agencies to ensure that legitimate shipments are not unnecessarily delayed. Does that include working with the State and local governments as well?

Mr. OVERACKER. Yes, Senator. And with respect to cargo release times and processing times, one thing I want to emphasize is that our ports of entry are open. Our CBP officers are clearing cargo. And so COVID has not impacted our cargo release process.

What we have experienced over time though—we see where there are instances where products may be regulated by FDA, and FDA would need to review them before they can be released by CBP. But if there are any delays, I am not aware of them right now. And part of the job of our CCRT is to resolve any potential holds that may exist so we can expedite that cargo.

And, Senator, I will be more than happy to take a closer look at what is going on in Nevada. But I assure you, our ports of entry are open and we are processing cargo.

Senator CORTEZ MASTO. And so, for instance, if a State Governor or a local government has issues, is there a direct contact that they could reach out to directly to get answers immediately?

Mr. OVERACKER. So the CCRT information portal, they have a web portal that is on *CBP.gov* where they take in inquiries. They triage those inquiries. They assign them to the appropriate port for resolution. And I myself even field inquiries directly. But I assure you, we will do everything we can to resolve whatever issue they may be experiencing under that.

Senator CORTEZ MASTO. I appreciate that. Thank you very much.

Let me talk a little bit—this has been discussed as well during this hearing, and I have heard this in my State as well through this pandemic. We have heard a lot about the gray market, which is a segment of the medical supply marketplace outside of the large manufacturers and distributors like McKesson or Cardinal that we can think of.

And *The Wall Street Journal* has also written about—how it describes it is as “an anarchic marketplace filled with legitimate vendors and traders, fly-by-night brokers, and opportunists who look to make a fast buck while operating in an arena with little transparency and fast-changing rules.”

Let me open this up to the panel, but let me start, Mr. Overacker, with you as well. Can you speak to the notion of this gray market PPE and what are the implications, and what are we doing to try to address it? I will tell you, my concern right now is that my government, the State of Nevada, and local governments are all competing with one another to get this PPE.

In fact, the concern I have is what I heard from local government, that typically they purchase masks. Once this pandemic hit, the mask price went up 66 percent. And not only were they not able to buy what they needed, they had to buy hundreds more masks than what they actually needed.

So what are we doing at the Federal level to address this gray market?

Mr. OVERACKER. So any time you introduce new actors in the supply chain, that exposes potential risks. So, from the CBP perspective, what we do for the facilitation piece is try to expedite the release of cargo from legitimate suppliers that we know; in other words, the entities that we have been dealing with over time and that we have a track record with.

As far as the gray market goods go, I mean the State and local governments are not just competing against themselves; they are competing globally, because this is a global pandemic and the supply around the globe is really under stress.

So what we try to do from a CBP perspective is, one, segment the risk so that we can expedite the legitimate shipments that we know. Focus in on those actors that are unknown to us. And with respect to gray market goods, when we think about “gray market,” we also have to recognize that in this pandemic not only do hospitals and schools and front-line operators need to have PPE, everybody needs PPE too.

So gray market goods are not always necessarily substandard, but they could be an alternative good for other actors who are not front-line responders.

Senator CORTEZ MASTO. Thank you to the panel. I appreciate it.

The CHAIRMAN. Senator Daines?

Senator DAINES. Thank you, Mr. Chairman.

It is long overdue that we end our reliance on foreign countries like China to produce medical equipment, supplies, and lifesaving drugs. That is why I have taken swift action to put America first in leading the efforts in Congress to support made in America manufacturing, as well as jobs.

I was able to secure \$10 billion in the CARES Act to accelerate the development and manufacturing of drugs and vaccines in the United States to treat and prevent the coronavirus. I also helped introduce legislation to end our reliance upon China for drugs and medical manufacturing and bring those jobs back to the U.S.

Being dependent on China is a threat to our national health. It is also a national security threat. America will be safer and it will be stronger when we bring our pharmaceutical and medical manufacturing supply chains and those jobs back to the United States.

Mr. Overacker, you mentioned in your testimony that China remains the largest source country for masks, which means they have significant control over these important supplies, putting America’s front-line workers at risk in the event of a public health crisis like we have seen.

I was pleased to see that there are provisions in the HEALS Act, the newly released COVID-19 relief bill, to encourage domestic manufacturing of personal protective equipment to the Strategic National Stockpile. This is critically important if we want to end our reliance on China for PPE and bring those jobs back to the United States.

My question is this: since the beginning of the pandemic, can you speak to the trends on imports of PPE and medical supplies from China and the work that DHS has been doing to combat counterfeit, substandard, and unapproved products like PPE?

Mr. OVERACKER. Thank you, Senator. Yes, currently, based on the data we see, China remains the largest supplier of masks to the United States by a wide margin over other countries such as Mexico, Canada, India, and Vietnam.

With respect to domestic production, there are domestic producers of N95 masks in particular. And any shift of production to the United States that would occur, we would also have to look at the secondary and tertiary supply chains that would be required to ensure that we have the materials to do so.

What CBP is currently doing with respect to imports from China is what we do on a daily basis. We scrutinize those imports by unknown or new actors just to try to see if these products are safe.

We work with FDA to determine whether or not these goods are regulated by FDA or not. And we even turn products over to the FDA for their review and to determine whether or not these are safe, or if they are FDA-approved products.

And in addition to that, we work closely with HSI. Any time we do have a counterfeit or a suspect product, we turn that information over to our partners with HSI so that we can work collaboratively on investigations.

Senator DAINES. Ms. Correa, in Montana and across the Nation we are seeing an uptick of coronavirus cases. While we are making significant progress on securing a COVID-19 vaccine for the American people as soon as perhaps October or November, it is critical that the United States is equipped with the PPE and the medical supplies necessary to combat this pandemic, especially with the upcoming flu season.

Ms. Correa, with regard to procurement, to what extent was DHS prepared to meet the COVID-19 crisis? Would you describe what gaps were found and lessons learned?

Ms. CORREA. Sir, thank you for your question.

This pandemic is of monumental proportions, of course, and it affected the entire country. So certainly, we had to adapt quickly to answering the call.

But typically, we have contracts. We use government-wide contracts. We have prepositioned contracts to respond to these types of things. Unfortunately, those contracts were not sufficient.

So what we have done is, we continue to vet vendors. In fact, as vendors come in and inquire or offer to sell anything, we have supplier verification teams that vet those vendors to ensure that they are proper sources of supply, that they actually have legitimate product that they can sell, and when that product would become available.

For any vendors who do not give us good information, or are not answering the questions, or appear suspect, we immediately refer them to the Inspector General for investigation.

Senator DAINES. That makes me—I have one last question for Mr. Overacker before I wrap up, but thanks for that update.

As I mentioned earlier, I helped secure \$10 billion in the CARES Act to accelerate the development and the manufacturing of COVID-19 vaccines and therapeutics. This funding was critical to the creation of Operation Warp Speed, which aims to deliver 300 million doses of a safe, effective vaccine for COVID-19 by January of 2021.

Mr. Overacker, in your testimony you mentioned that CBP's COVID-19 Cargo Resolution Team works at HHS to facilitate importation of equipment and materials in support of Operation Warp Speed.

Could you give me an update on these efforts to date? I am running out of time, so please make it brief.

Mr. OVERACKER. Senator, we have had several meetings with HHS and Moderna. We have a meeting scheduled with them on Thursday. Our intention is to identify what they need to have imported, whether it is production equipment, and then make certain that we expedite that.

We anticipate that they will begin importations in August. But in addition to the production equipment, all of the other materials that will be needed to deliver 300 million doses of vaccine—such as 300 million syringes and 300 million glass vials, 300 million cotton swabs, whatever it is—we are going to work with them to identify what they need, and we will expedite getting that into the country for them.

The CHAIRMAN. Senator Whitehouse?

Senator WHITEHOUSE. Thank you, Mr. Chairman, and thank you all for a long morning. I appreciate your service.

Ms. Correa, when you are doing your purchasing, whom are you buying for?

Ms. CORREA. Generally, we are buying for the Department of Homeland Security.

Senator WHITEHOUSE. For FEMA?

Ms. CORREA. For all of DHS.

Senator WHITEHOUSE. But in this case, primarily—

Ms. CORREA. In this case, FEMA was buying on behalf, or for HHS in support of Federal, State, and local—

Senator WHITEHOUSE. And the Strategic National Reserve?

Ms. CORREA. Yes.

Senator WHITEHOUSE. Okay. So if I were—say the State of Rhode Island and I came to you, you are not there to help me? You are there to help the Federal agencies, FEMA, HHS, and so forth?

Ms. CORREA. Exactly. Yes, sir.

Senator WHITEHOUSE. So that is what your testimony is—

Ms. CORREA. That is correct. I oversee the processes.

Senator WHITEHOUSE. And the fact that a State is thrown into this melee of competition is something that you are not in a position to remedy, because you do not work for the State.

Ms. CORREA. That is correct.

Senator WHITEHOUSE. Mr. Francis and Mr. Overacker, you have both given powerful testimony about the extent of the fraud in this marketplace. Indeed, you have said consumers have no way to know if these PPE items are in fact legitimate, or if they will work, if ordered from third-party marketplaces or non-medical websites.

Would you characterize the current market out there as toxic to some degree in terms of the amount of fraud and mislabeling and defective products that are being sold in it?

Mr. FRANCIS. Thank you, Senator.

Senator WHITEHOUSE. Toxic, dangerous, use your word. I am not trying to put a word in your mouth, I am just trying to get a simple

description of how dangerous you think this marketplace is for the buyer.

Mr. FRANCIS. I think dealing with this pandemic and the global anxious audience—you know, there is a high demand of equipment and PPE, and it is very vulnerable. And so we are seeing this very challenging environment with marketplaces, social media platforms, the sales of these goods. It is really disheartening.

Senator WHITEHOUSE. So, very vulnerable? Very challenging? Rife with fraud? All fair descriptions?

Mr. FRANCIS. Yes, sir.

Senator WHITEHOUSE. Do you agree, Mr. Overacker?

Mr. OVERACKER. Yes. And I would say that any time you are dealing with e-commerce, when you are dealing with unvalidated or unknown entities that are selling products online, there is an inherent risk. And that is one of the reasons why at CBP we have launched what we call a section 321 data pilot that refers to low-value shipments, where we are working closely with platforms—

Senator WHITEHOUSE. Let me get to some of the areas—

Mr. OVERACKER [continuing]. And areas to get additional—

Senator WHITEHOUSE. Yes; you are a little bit off the point of my question, so let me interrupt, because I have 2 minutes left.

What do you know about the extent to which either the Secretary or the White House was informed about the hazards of the marketplace? I am assuming that you have reported this to your superiors, and that works its way up through the system, but is it correct that the Secretary and the White House are aware of the dangers and hazards of this marketplace?

Mr. OVERACKER. They are most definitely aware of the dangers and hazards of the e-commerce marketplace. The President issued a memorandum over a year ago asking DHS to put together an action plan for how to address vulnerabilities in the e-commerce marketplace. And so they are very much aware.

Senator WHITEHOUSE. Okay—

Mr. OVERACKER. And I see—

Senator WHITEHOUSE. Mr. Francis?

Mr. FRANCIS. To Mr. Overacker's point, I have been part of the presidential memorandum on counterfeiting and the trafficking of counterfeit and pirated goods that was issued by the President in April of 2019.

Senator WHITEHOUSE. What is discouraging to me—and I will just close with this statement—representing Rhode Island, is that we got thrown into this marketplace on our own with no support from the Federal Government in the procurement, as Ms. Correa said, with full knowledge that this was a dangerous and hazardous marketplace, and with no real support or interest in fixing it.

And the result was sort of a clown show performance. Our Governor talks about fighting to try to get a truck full of PPE into Rhode Island through the FEMA process and, although you can track your Amazon package to where it is, nobody could tell us where the damn truck was.

So for days, and through multiple agencies, we had to hunt the truck that at the peak of our surge was bringing desperately needed PPE. And sure enough, glory day, the truck arrived. The truck was empty.

That is the kind of nonsense that we have had to put up with because of the absence of real leadership here from the Federal Government.

The CHAIRMAN. Now the most patient Senator here is the last speaker, the Senator from Washington State.

Senator CANTWELL. Thank you, Mr. Chairman.

I wanted to ask Customs and Border Patrol about just the issue of resources and people. Because I look at this two ways. One, we certainly in the State of Washington have over 52,000 people who have been infected with COVID. We had one of the first cases in the Nation, and we have lost lives. But the issue of personal protective equipment is—we have had an incident where I think the Governor had to return over 200,000 masks in a 2-week time period because the FDA took a foreign manufacturer off the authorized list.

And then we have had the opposite, where we have actually gotten production companies that have switched modes of what they were manufacturing and tried to help the effort, and then they are trying to produce both surgical and N95 masks and still have not gotten everything they need to move forward on the approval of that.

So I look at that and I think, what is the underlying issue here? And so I want to ask whether you feel like you have the people and the resources to meet the challenge of this job?

Mr. OVERACKER. So, Senator, with respect to processing cargo as it arrives in the United States, or even export cargo, Congress and the Senators have been very generous with CBP with respect to our CBP officer resources, and we are very grateful for that.

And we have done a very good job over the last 5 years of turning around our hiring capabilities so that we are now in a better position than we have been in in years with respect to our CBP officer resources.

And these are the resources that work at our ports of entry. These are the first line of defense with respect to processing cargo and getting cargo into the United States.

Senator CANTWELL. Well, listen. I am from a big cargo State, and I definitely understand about cargo. But my point is, do you have specially trained officers in this area of PPE equipment?

Mr. OVERACKER. Not necessarily, but through our Pharmaceuticals, Health, and Chemicals Center of Excellence and Expertise, we work with that industry to understand what their needs are. And then we try to expedite whatever processing we can on their behalf. But we rely on the private sector to explain to us what those needs are.

Senator CANTWELL. I am not talking about the needs now. I am talking about not letting products into the country that do not qualify. So I am curious as to whether you are coordinating with DHS and FDA to ensure that the PPE equipment that is imported meets the quality standards so that we do not have product running around, and people assuming that we have product, and then having it have to be recalled or reclaimed by our States.

Mr. OVERACKER. Yes, Senator. We work very closely with FEMA. And you mentioned emergency use authorization, I believe. One of the things that FEMA communicates to us are who are the author-

ized manufacturers of products, so that we can look at that to segment the risk.

We turn over product to FDA for their review and approval on a regular basis. And whenever FDA makes changes to those emergency use authorizations and identifies changes in those manufacturer lists, then we adjust our capabilities accordingly using our automated systems.

Senator CANTWELL. Well, I would suggest we have specially trained people to help with this. I think, look, we do not want to create three or four steps. And there are many aspects of the COVID crisis where we have had to knock down those three or four steps, whether it was testing and getting our universities up to speed on testing, or a whole variety of things.

So I would definitely want to see more coordination between CBP and the FDA on those issues. There is just no reason we should allow product in that we know is defective or not going to help.

But the other issue is, I feel like we are not being aggressive enough in really understanding and communicating with our manufacturers. I think Korea decided they were just, they were like, we are just going domestic production. That is it. We are going domestic production.

So you want to get the supply chain and the authority and the lines of responsibility to those manufacturers so we can move ahead. We should not have millions of masks—this is what is happening to us right now—millions of masks, both N95 and other, sitting stored somewhere in Pioneer Square when we have health-care workers who are dying.

They are in need of those products. So I want to expedite this product process and make sure that we know what the U.S. manufacturers are required to do, that they are meeting this process, and that we expedite that. So if we are going to go this route of a domestic route—and you know I am proud of these companies that have switched over—we need to make sure that we can do it in safe but timely fashion.

Thank you, Mr. Chairman.

The CHAIRMAN. Well, thank you very much.

I want to thank the witnesses and all my staff who cooperated in getting this done at a reasonable hour on a very important subject that we need to continue to discuss. And I thank the staff for putting together a very difficult hearing, under the circumstances of how these hearings are held because of the pandemic.

And I hope that we, as a result of this hearing, do some things that will continue to improve the reliability of our medical supply chain. Congress must ensure that the administration takes all necessary steps to properly protect the integrity of this chain and the supplies that are in it. We must work together to make sure that our health-care workers and hospitals receive the supplies they need, and that they can have a safe workplace.

We must also engage with U.S. manufacturers, suppliers, and distributors to quell PPE shortages caused by the pandemic. Today we have highlighted many of the problems our medical supply chain has recently faced. We must discuss serious policy solutions to provide safely manufactured medical supplies for our health-care workers and hospitals.

With that, do we have an announcement on the questions? Oh, it is right here in the last sentence. The deadline for our members to submit questions for answering in writing is August the 4th at the close of business.

Thank you all for attending and for faithfully trying to answer our questions. The meeting is adjourned.

[Whereupon, at 1:11 p.m., the hearing was concluded.]

A P P E N D I X

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF SORAYA CORREA, CHIEF PROCUREMENT OFFICER,
DEPARTMENT OF HOMELAND SECURITY

INTRODUCTION

Chairman Grassley, Ranking Member Wyden, and distinguished members of the committee, thank you for the opportunity to appear before you today to discuss how procurement enables supply chain integrity at the U.S. Department of Homeland Security (DHS or the Department).

I am Soraya Correa, the Department's Chief Procurement Officer. I have been a career civil servant for more than 39 years, and I am proud to say that I have been with DHS since its inception. At DHS, I have served in various leadership positions in procurement and program management including as the Head of the Contracting Activity for U.S. Immigration and Customs Enforcement and Associate Director of the U.S. Citizenship and Immigration Services Immigration Records and Identity Services (formerly the Enterprise Services Directorate). I am deeply committed to the missions of the Department.

In my current position, I oversee the work of 10 contracting organizations composed of approximately 1,400 contracting professionals that provide operational procurement services to DHS Components, Directorates, and offices across the country. In fiscal year 2019, DHS procurement professionals obligated \$23.9 billion through over 74,000 procurement actions. My office manages the Department's procurement policy and processes and provides enterprise-level procurement tools and contract vehicles to support the DHS contracting organizations. I am an advocate for innovative procurement approaches, reducing administrative burdens, and ensuring the procurement workforce has the tools necessary to conduct their work with integrity to enable the DHS mission.

I am honored to serve in this role and to lead the hardworking professionals who procure the goods and services to meet the Department's mission needs. We are proud to buy a wide array of products and services including the supplies needed to respond to disasters or other national emergencies.

PROCUREMENT ENABLES SUPPLY CHAIN INTEGRITY

As our country and the Department were confronted by the COVID-19 pandemic, the DHS procurement organization quickly adapted and continues to meet mission needs. Our organization understands emergency contracting operations and managing supply chain risk, including the importance of ensuring contracts and orders are awarded to only those contractors who are deemed responsive and responsible in accordance with the Federal Acquisition Regulation (FAR).

Policy and Oversight Actions

As with other major disaster declarations and national emergencies, I invoked all special emergency contracting flexibilities within my authority under the FAR as the DHS Senior Procurement Executive, immediately after the President declared a national emergency for COVID-19. Specifically, and working in partnership with the Department's Chief Financial Officer, I increased the purchase card limit so that the Department, including the Federal Emergency Management Agency (FEMA) in its emergency response capacity, could more easily procure larger volumes of emergency supplies and services. I eliminated certain paperwork requirements so that

DHS could purchase COVID-19 related supplies and services quickly, cutting the normal procurement lead time from weeks to days or even hours.

I also instituted improvements within the regulatory framework so the DHS acquisition team, including program managers, contracting professionals and contractors, could continue work without disruption in a virtual environment. This effort included eliminating the requirement for hard copy documents, wet signatures, notarization, seals on bonds and other scenarios. These flexibilities allowed DHS, including FEMA in its emergency response role, to quickly support urgent needs for COVID-19 supplies and services within the regulatory framework. These flexibilities went into effect in March 2020 and will remain in effect as appropriate to ensure continued timely support of COVID-19 response and recovery operations. Throughout this process, DHS procurement professionals performed required contractor responsibility determinations before awarding a contract.

Meaningful Communications

In early March 2020, I began communicating with industry and DHS contracting staff on a regular basis to ensure that everyone was aware of the flexibilities available to them. I regularly held conference calls with the contracting activities, legal counsel, and others to ensure DHS Components had all the information and tools necessary to respond to mission needs. As a broader DHS community, we answered industry questions and collaborated on ways to accomplish our mission remotely or on site as essential employees.

In April 2020, we initiated weekly virtual meetings with industry associations to discuss issues related to COVID-19. These discussions focused on the supply chain and how industry could support DHS operational requirements in response to the pandemic. We also hosted industry events focused on return to the workplace. In these sessions, we discussed and addressed industry's concerns and perspective as they plan to return to the workplace. These industry association meetings continue because they have proven to be an exceptional way to stay connected and transparent with business entities supporting or interested in supporting DHS with the COVID-19 response. We not only answer their questions, but also provide critical and timely information for them to disseminate to their members.

Process Enhancements

As we began to see a significant surge in incoming inquiries from industry and offers of help to DHS in response to the pandemic, I established two teams at DHS composed of subject matter experts to support our COVID-19 response efforts: the Supplier Verification Team and the Procurement and Acquisition Innovation Response (PAIR) Team. These teams serve as centralized points to expeditiously review, vet, and refer information about companies offering COVID-19 solutions to the appropriate Components or offices within DHS. These teams examine the potential viability of a supplier based on several factors including the extent to which the supplier has been in the business of selling the related products or services. The teams compile reports and disseminate them to the DHS contracting organizations and senior program officials. The work of these teams supplement the Contracting Officers' efforts and provide information to support them as they conduct market research and perform responsibility determinations. Once these teams provide market research information, it becomes the responsibility of the acquisition team to conduct further checks and/or testing of the products.

The Supplier Verification Team sub-divided itself into two teams; one focuses on personal protective equipment (PPE) (*i.e.*, aligned with the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) definition of PPE) and the other focuses on non-PPE (*e.g.*, COVID-19 test kits). Early in the pandemic response, we recognized that shortages of PPE would affect the DHS front-line mission operations, as well as FEMA's role in supporting emergency response efforts. Thus, the Supplier Verification Team researches vendor leads, conducts phone screening, and vets vendors through publicly available databases, such as the Better Business Bureau and the System for Award Management. This vetting process examines the legitimacy of a supplier based on several factors including the extent to which the supplier has been in the business of selling the specific PPE product, has existing inventory located within the United States, has existing mechanisms to receive the products domestically, including existing contracts or relationships with manufacturers, the model numbers of products offered, and whether the supplier would require for DHS to pay for the product in advance of receipt. This initial review provides valuable market research information for our procurement professionals who formally enter into the contracts and orders for PPE.

The PAIR Team, unlike the Supplier Verification Team, reviews and researches industry inquiries that offer innovative approaches and solutions submitted in support of DHS's response to COVID-19. The PAIR Team conducts market research to determine the potential viability of offered solutions and shares their findings with program officials and contracting personnel across DHS. Industry capabilities and offerings reviewed to date include information technology (IT) solutions for contact tracing, health screening, alternatives to PPE, disinfection products, medical supplies, and others.

As part of the Federal efforts to scour the globe for PPE and consider all opportunities, FEMA and its Federal partners explored thousands of leads both across the country and overseas. Whether a lead came from the White House Coronavirus Task Force, members of Congress representing businesses in their State, or through an enterprise's unaffiliated inquiry, FEMA processed all leads through standard vetting procedures and the Federal procurement process. To be clear, DHS follows the law and all applicable procedures, including those prescribed by the FAR, in entering into contracts. To ensure the integrity of the process, FEMA established a firewall between those responsible for identifying leads and those responsible for accomplishing the purchase.

Additionally, my office, in partnership with the Department's Office of the Chief Readiness Support Officer, established a centralized ordering process to utilize the funds DHS received under section 3618 of the CARES Act for Departmental PPE needs.

Innovative Solutions

We have used various methods across the Department to seek innovative solutions that support our COVID-19 response effort. I have long been an advocate of innovative approaches to our work, and the COVID-19 response is no exception.

FEMA used an open solicitation that immediately alerted industry to all the COVID-19 PPE and related items that FEMA needed. The open solicitation approach covered a broad number of items and saved significant time compared to posting separate solicitations for each item. FEMA's approach avoided a lengthy evaluation process while obtaining necessary items at fair and reasonable prices as quickly as possible.

DHS released a general solicitation in April 2020 using our Commercial Solutions Opening Pilot Program Authority for innovative commercial solutions relevant to the DHS response to COVID-19 and other microbial threats. The purpose of the solicitation is to obtain innovative commercial products that may help meet our new and emerging mission needs that have resulted from the COVID-19 pandemic and to prepare us as we consider future outbreaks or similar threats. Vendors may propose solutions in any of several broad categories to include PPE alternatives, decontamination or disinfection solutions, contact tracing solutions, screening solutions, and other IT categories. The solicitation will remain open until August 31, 2020.

In addition, we partnered with other DHS offices and industry to identify innovative ways to obtain and distribute needed supplies and to enable greater use of the supplies in our inventory. For example, the DHS procurement team worked with U.S. Customs and Border Protection to obtain a donation from Exxon Mobil Chemical Company of medical-grade hand sanitizer for distribution by the FEMA National Response Coordination Center. Approximately 20,000 gallons were delivered weekly to first responders and hospitals over a 6-week period.

CONCLUSION

The Chief Procurement Office remains fully committed to ensuring the Department has the products and services needed to fulfill its critical mission to safeguard the American people, our homeland, and our values. We will continue to look for every opportunity to increase the efficiency and effectiveness of our policies and processes to ensure the integrity of the supply chain throughout the procurement process. We will seek out new ideas and innovations to get the best possible solutions to the people in the field as quickly as possible, while being good stewards of taxpayer dollars.

Thank you again for the opportunity to testify today, and I look forward to your questions.

U.S. Department of Homeland Security

Washington, DC 20528

Assistant Secretary for Legislative Affairs

August 13, 2020

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

Dear Chairman Grassley:

I write to respectfully request this letter be entered into the hearing record to correct a statement made by the Department of Homeland Security (DHS) at a recent hearing.

The DHS Chief Procurement Officer, Soraya Correa, testified before the Senate Committee on Finance on July 28, 2020, at the hearing entitled, "Part 1: Protecting the Reliability of the U.S. Medical Supply Chain During the COVID-19 Pandemic." During her testimony, she was asked why the Federal Emergency Management Agency (FEMA) awarded a contract to the company Fillakit. Ms. Correa stated that Fillakit had an emergency use authorization (EUA) provided by the Food and Drug Administration (FDA).

Subsequent to the hearing, Ms. Correa learned she had received inaccurate information concerning Fillakit having an EUA. FEMA contracting officials confirmed that Fillakit did not receive an EUA. Instead, FEMA awarded the Fillakit contract after they confirmed that the FDA allowed the type of alternative test kit media that Fillakit proposed. FDA has also confirmed that Fillakit did not receive an EUA for the test kits acquired by FEMA. Prior to signing the contract, FEMA did perform the required reviews to determine that Fillakit was eligible for a contract award and able to perform the contract before FEMA signed the contract.

This letter is submitted to ensure that the record is accurate. Thank you for your understanding and for your support of this request.

Respectfully,

Beth Spivey
 Assistant Secretary for Legislative Affairs

QUESTIONS SUBMITTED FOR THE RECORD TO SORAYA CORREA

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

LOW-INCOME COMMUNITIES

Question. Last month, the CDC reported that minorities are being disproportionately impacted by COVID-19 and are 3 to 4 times more likely to be hospitalized by the virus. Many of these individuals are also low-income, and are struggling to afford housing, food, and medical care. It is paramount that we do not overlook the needs of this most vulnerable population during the pandemic.

How is your office working with industry and other DHS components to ensure that hospitals that serve low-income communities receive lifesaving medical equipment?

Answer. The U.S. Department of Homeland Security's (DHS) Office of the Chief Procurement Officer (OCPO) is not authorized to provide medical equipment to hospitals. The U.S. Department of Health and Human Services (HHS) has this authority under title 42. The OCPO will assist HHS in meeting its mission if called upon to do so.

PRIORITIZING BUSINESSES

Question. How is your office prioritizing minority-owned, veteran-owned, and women-owned small businesses who seek to provide aid and support to the Federal Government during the pandemic? Please provide data on the number of small businesses that have reached out to your office with offers of aid. Please break out the

data by type of small business, product and/or service offered, and outcome of these discussions. If your office does not collect this type of data, please explain.

Answer. OCPO established a team to receive general information from companies that wanted to aid DHS during the pandemic, but the team did not gather information on the size of the companies that were offering the aid. This type of information was not needed to determine whether the company was a viable supplier.

The U.S. Department of Homeland Security (DHS) remains a leader in Federal small business contracting. Preliminarily, the available data indicates that DHS will award over \$21 billion in prime contracts and that \$7.6 billion of that amount will be awarded to small businesses. This equates to almost 36 percent of DHS dollars awarded to small businesses. For small disadvantaged businesses, the preliminary FY 2020 prime contracting data indicates that over \$3.2 billion dollars or 15.4 percent of dollars were awarded to these firms. This amount is 10.4 percent higher than the statutory goal of 5 percent.

ADVANCE PROCUREMENT

Question. What steps can DHS and its components take to procure goods and services in advance of national emergencies in the future? From a procurement perspective, what lessons have we learned from the coronavirus pandemic?

Answer. DHS routinely assesses future needs as part of its strategic sourcing and category management program. If there is a likely need to procure goods and services to meet DHS's mission needs in the future, DHS will consider creating contracting vehicles to ensure that when the need arises, DHS can procure items efficiently.

While we will continue to identify lessons learned as we progress through the pandemic, we have identified the following lessons learned:

- Consistent and persistent communications, collaboration, and connectivity channels, both internally and externally with industry and partner agencies are critical.
- Performing the contracting process through electronic tools allowed DHS to award and administer contracts remotely so the DHS workforce and industry counterparts remained safe while meeting DHS's mission needs.
- The COVID-19 Commercial Solutions Opening Pilot solicitation created an opportunity for DHS to find innovative solutions that could help with the COVID-19 response, as well as respond to similar microbial threats in the future.
- Establishing procurement flexibilities immediately after the national emergency was declared allowed the Heads of the Contracting Activities to respond nimbly to emerging operational needs. Providing support to the operational teams as issues arose including assessing inquiries, interpreting section 3610 of the CARES Act and addressing staffing needs enabled the contracting activities to remain focused on purchasing the needed items efficiently.

SECURE THE SUPPLY CHAIN

Question. What steps is your office taking to secure the U.S. medical supply chain as we go into the fall and beyond?

Answer. U.S. Customs and Border Protection (CBP) has the lead within DHS, in concert with other offices, on securing the medical supply chain. CBP will support HHS and others as they determine which medical supplies are needed for DHS's mission and the appropriate steps needed to ensure defective and counterfeit items are not ordered or received. OCPO has added safeguards to its review of vendors that do not have a history of providing the Department with a product. In these cases, the contracting officer (CO) will perform additional checks to ensure DHS does not award to a company that is likely to deliver defective or fraudulent items.

QUESTIONS SUBMITTED BY HON. RON WYDEN

ICE PPE

Question. The health conditions at ICE detention facilities during the pandemic have been appalling. More than 3,700 detainees and hundreds of staff have tested positive for the disease. Prior to the pandemic, there was a long list of disturbing

issues such as overcrowding, abusive and negligent practices, and lack of adequate medical care. In recent weeks, the inspector general has reported that ICE doesn't have sufficient PPE. Such issues fit with previous inspector general reports that raised concern inadequate pandemic preparedness, including having enough PPE on hand, at ICE and other DHS agencies.

As the chief procurement officer for DHS, what is the status on PPE now?

Answer. The status and inventory management of personal protective equipment (PPE) at ICE facilities is monitored and overseen by appropriate ICE officials. When a need for additional PPE is identified for employees or detainees, it would normally be procured by ICE contracting officials. In an effort to support ICE during the pandemic, the procurement of some PPE was coordinated through the DHS Office of the Chief Readiness Support Officer and the Office of Procurement Operations at DHS Headquarters. Please note, there is no shortage of PPE at ICE-controlled detention centers. Some facilities are the responsibility of State and local governments while others are managed by an ICE contractor. In those cases, the contractor is required to provide PPE for their employees, visitors, and detainees. As of August 31, 2020, none of these contractors have reported to the Office of the Chief Procurement Officer that they have shortages of PPE.

No vendor has reported to the ICE Office of Acquisition Management any issues of acquiring PPE. Vendors are required to adhere to all detention standards contained in the contracts and agreements, including health and safety requirements, and ICE ERO issued Pandemic Response Requirements to all vendors that incorporated additional health and safety requirements. Provision of PPE is already within scope of current detention contracts and agreements, and vendors were reminded of this earlier this year.

Question. Is it possible for ICE to ensure the health and safety of everyone at these facilities, if it lacks sufficient PPE?

Answer. The Centers for Disease Control and Prevention (CDC) is the authoritative source for information regarding health and safety standards. The appropriate ICE officials are responsible for implementing the safety protocols at ICE facilities. For instance, during the intake process ICE tests detainees who arrive at ICE-owned facilities for COVID-19. ICE houses detainees separately (cohorts) from the general population for 14 days after their arrival and monitors them for symptoms. This process protects the new detainee who tests positive for COVID-19 and helps to prevent the spread of COVID-19 to others in the facility.

Further, the ICE Health Service Corps (IHSC) provides direct daily care to detainees housed at 20 IHSC designated facilities throughout the Nation. IHSC provides medical case management and oversight for all other ICE detainees housed at non-IHSC-staffed detention facilities across the country. As previously mentioned, no vendor has reported to the ICE Office of Acquisition any issues of acquiring PPE.

ATD

Question. Do you agree that ICE must maximize its use of alternatives to detention to reduce the risk to staff and detainees immediately?

Answer. ICE has many options to reduce the potential spread of COVID-19 among detainees and staff at detention facilities. In March, ICE's Enforcement and Removal Operations convened a working group between medical professionals, disease control specialists, detention experts, and field operators to identify enhanced steps to minimize the spread of the virus. Based on CDC's guidance, ICE has since evaluated its detained population to identify those who might be at higher risk for severe illness as a result of COVID-19, and to determine whether continued detention of those individuals was appropriate. Resultingly, ICE released over 900 individuals after evaluating their immigration history, criminal record, potential threat to public safety, flight risk, and national security concerns. This same methodology is currently being applied to other potentially vulnerable populations currently in custody and while making custody determinations for all new arrestees.

Additionally, detainees who meet CDC criteria for epidemiologic risk of exposure to COVID-19 are housed separately from the general population. ICE places detainees with fever and/or respiratory symptoms in a single medical housing room, or in a medical airborne infection isolation room specifically designed to contain biological agents, such as COVID-19. This action prevents the spread of the agent to staff, other individuals at the facility and the general public. ICE transports individuals with moderate to severe symptoms, or those who require higher levels of care

or monitoring, to appropriate hospitals with expertise in high-risk care. Detainees who do not have fever or symptoms, but meet CDC criteria for epidemiologic risk, are housed separately in a single cell, or as a group, depending on available space. ICE reviews CDC guidance daily and continues to update protocols to remain consistent with CDC guidance.

QUALITY OVERSIGHT

Question. In a recent interview, you said it is important that DHS maintain the “right level of compliance” in its contracting activities, but that not every “i can be dotted or t crossed.” You expressed concern that 100-percent compliance might mean the Department would “not be getting things out as quickly as you need to.”

This interview was posted online in May, in the middle of the COVID-19 pandemic, when FEMA’s contracting practices, which are under your purview, have had serious problems. FEMA has entered large contracts with companies that had no prior record of government contracts or importing medical supplies. Some of these companies were formed just days before being granted a FEMA contract, and some contracts have since been canceled for non-performance.

But DHS’s contracting problems didn’t start with the coronavirus. The Inspector General and Government Accountability Office have expressed concern for years about contracting processes at DHS and its agencies. To this end, I would like to understand the guard rail on FEMA’s procurement process.

Please explain what has been done to “right the ship” and make sure there is increased oversight regarding quality of the procured PPE. Please explain how these procedures are applied to imported products, versus domestically produced products.

Answer. As part of the contract for distribution, both the Federal Emergency Management Agency (FEMA) and the Defense Logistics Agency’s (DLA) vendors have an extensive PPE quality assurance process that includes fraud detection, product sample review, and product inspection/testing. The vendor also provides for replacement of damaged goods or technical assistance if the situation arises. As an example, a few nursing homes reported challenges with the Level 3 “blue gowns,” and in response, the vendor provided more detailed instructions for the customer.

In each direct vendor shipment, the vendor provides contact information for the staff should any issues arise with PPE shipments. If PPE items are damaged or missing, staff can contact the vendor with any issues pertaining to shipments. Once the customer contacts the hotline, if a replacement is needed, items are usually shipped within 24–48 hours. If and when fraud is discovered with imported shipments, notification goes to acquisition teams for fraudulent activity and CBP for future screening.

These quality standards are also used during the Department’s inspection and acceptance activities for PPE items and apply whether the item is manufactured domestically or imported from another country. DHS relies on these standards to ensure PPE performs effectively. Additionally, CBP conducts inspections of shipments of imported products and works with ICE Homeland Security Investigations to prevent as well as find and remove counterfeit and defective PPE from the medical supply chain. While this effort is independent of the contracting process, these organizations are available to assist with inspection of PPE procured for the DHS workforce, when needed.

CONTRACTING PROCESS

Question. Please explain what has been done to ensure the bidding and contracting process in the context of the pandemic is meeting the Federal Acquisition Regulations and other procurement requirements.

Answer. DHS trains each contracting professional on acquisition related laws, regulations, and policies and warrants COs commensurate with the level of their training and experience. DHS also uses appropriate checks and balances to ensure procurements are compliant with Federal and agency regulations and policies. For example, in accordance with the Homeland Security Acquisition Manual 3004.7002, with limited exceptions all contract actions over \$500,000 are reviewed by the policy branch or at least one level above the CO within the chain of command. The OCPO performs periodic independent oversight reviews to verify compliance with these reviews as well as other acquisition laws, regulations and policies.

OVERSIGHT RESPONSIBILITIES

Question. As the DHS Chief Procurement Officer, what oversight responsibilities do you have related to reviewing component procurements, including procurement by FEMA? Please provide citations and thresholds where appropriate.

Answer. OCPO has oversight responsibilities for DHS procurements. The Chief Procurement Officer (CPO) ensures each contracting activity has access to DHS procurement experts to support complex, high value or other high interest procurements through a Procurement Strategy Roadmap. The CPO also reviews and approves various pre-award documents including Acquisition Plans valued over \$100 million and all Justifications and Approvals for other than Full and Open competition exceeding the statutory thresholds established in the Federal Acquisition Regulations (FAR).

Additionally, the Procurement Innovation Lab and Oversight and Pricing Branch are available to assist Component contracting activities in developing solicitations at all levels, but generally they assist on those contracts valued above \$25 million, to ensure the use of innovative methods to efficiently and effectively procure goods and services. OCPO reviews the contract files of half of the DHS contracting activities each year. These reviews include a statistically significant sample of contract actions awarded in the previous 12 months and ensures the contracting activities consistently comply with acquisition laws, regulations and policies. The review also includes the sharing of best practices and identification and elevation of any problems for prompt resolution.

Question. How, if at all, has your review of procurements changed during the response to COVID-19? For example, has your review of certain high-dollar procurements been waived to more quickly award contracts in response to COVID-19, and if so, what procurement risks does that pose?

Answer. The CPO did not change its oversight of procurements in response to COVID-19. However, the CPO directed the Component Heads of the Contracting Activities (HCA) to make use of certain flexibilities authorized in the FAR or acquisition policy to award COVID-19 contract actions more efficiently and expeditiously, where necessary. In addition, the OCPO issued Homeland Security Acquisition Manual (HSAM) Class Deviation 20-01 to suspend certain requirements to facilitate the rapid procurement of supplies and materials required during the COVID-19 emergency. These requirements include temporary suspension of:

- *One-Bid Award Questionnaire.* COs are not required to complete the questionnaire when only one quotation/offer is received in response to a solicitation.
- *Procurement strategy roadmap (PSR).* Rather than formal briefings or written documentation for those procurements meeting the HCA's PSR threshold, HCAs are required to keep the CPO informed of COVID-19 related procurements.
- *Acquisition Planning Forecast System (APFS).* Completion of the APFS record is suspended for COVID-related actions over the simplified acquisition threshold.
- *Buy American Act (BAA) advance review and approval requirements.* While the CO continued to implement FAR 25.103 and 25.202 to purchase American made products, the CPO delayed the notification that a needed COVID-19 item was not available as an American made product at the quantities and delivery schedules required. Instead of notifying the CPO prior to soliciting industry for a non-American made product, the CO notified the CPO of the non-availability concurrently with making the contract award. This did not suspend a CO's responsibility to ensure the contract file for the effected procurement includes sufficient documentation to support the exception to the BAA.

COMPONENTS RESPONSIBILITIES

Question. What responsibilities do Components' Heads of Contracting have to ensure that contracts being awarded in response to COVID-19 have clear requirements and are going to responsible contractors that are capable of fulfilling them?

Answer. The HCAs are required to ensure that each award is made to a responsible contractor and that the contracting process complies with all applicable laws, regulations and policies. The HCAs also foster collaboration with requirements' own-

ers to ensure that the statements of work are clear, and the customers' needs are met.

STRATEGIC NATIONAL STOCKPILE

Question. Evidence suggests that the United States was poorly prepared for a nationwide event like a pandemic, despite years of warning that an influenza type virus could strike. The Strategic National Stockpile, as well as stores kept by DHS and FEMA appear insufficient to address the COVID-19 crisis.

Please clarify how prior to the pandemic your office worked to ensure sufficient procurement occurred to stock and replenish stockpiles of PPE, medicine, and other critical products.

Answer. Section 319F-2 of the Public Health Service Act (42 U.S. Code §247d-6b) authorizes only the Secretary of Health and Human Services to make procurement decisions and take procurement actions regarding the national stockpile. The Act allows the Secretary of Homeland Security to provide consultation services. For additional information on this matter, I respectfully refer you to HHS.

POTENTIAL INCREASES

Question. Given the challenges experienced procuring medical and testing equipment and supplies, what steps are DHS and its components taking to prepare for procuring the goods and services needed to respond to potential increases in COVID-19 cases now and in the future?

Answer. DHS is continuously assessing and preparing to meet the procurement needs of the Department in response to COVID-19. During the initial wave of the pandemic, OCPO was a leader in immediately establishing working groups to support the DHS response to COVID-19. These efforts included establishing vendor vetting teams for PPE and non-PPE, and centralized processes for reviewing informal and formal innovative solutions from industry.

Working with Components and other lines of business at the Headquarters level, OCPO has a centralized process for procuring PPE and is currently procuring strategically sourced contract vehicles for COVID-19 testing solutions. These and many other actions help prepare DHS to meet future internal needs in response to the pandemic. DHS is taking other steps to be ready to procure goods and services if there is an increase in COVID-19 cases, but many of these steps are outside of the procurement office's purview.

NATIONAL INTEREST ACTION CODE

Question. A key mechanism available to agencies, Congress, and the public for tracking use of contracts in response to COVID-19 is the National Interest Action code. We understand that, at the current time, the National Interest Action code for COVID-19 will expire on September 30, 2020.

Given the increases in cases over the past month, do you anticipate extending the National Interest Action code? If so, for how long?

What factors do you consider when making the decision of how long to keep a National Interest Action code open?

Answer. The National Interest Action (NIA) code for COVID-19 has been extended through March 31, 2021.

Question. What factors do you consider when making the decision of how long to keep a National Interest Action code open?

Answer. DHS, along with the U.S. Department of Defense (DoD), considers several factors when recommending the extension of a NIA code. Two of these factors include looking at whether procurement thresholds raised pursuant to Federal Acquisition Regulation Part 18 in response to the emergency have returned to their original levels, and whether the number of actions with the NIA code reported to the Federal Procurement Data System have significantly decreased.

Question. To what extent do you consider the needs of, for example, our committee and others in Congress, as well as the American people, to be able to transparently identify information about contracts the Federal Government is awarding in response to COVID-19?

Answer. The DHS CPO considers transparency to the American people to be fundamental for all procurements. Therefore, DHS follows all applicable laws, regula-

tions and policies to ensure transparency. In the case of COVID-19, the Office of Management and Budget in their Memo 20-21 directed all agencies to track COVID-19 dollars obligated using a Disaster Emergency Funding Code (DEFC) in the financial systems, not the NIA code. This DEFC is then tied back to contract and grant awards on the *USASpending.gov* website. This process maximizes transparency to Congress and to the American people. In addition, it fulfills the requirements under the Federal Funding, Accountability, and Traceability Act, which was further refined under the Data Act. *USASpending.gov* provides information on all contract and grant spending in one place, making it easy for the public to find and use this information.

Note that the NIA code policy was created before *USASpending.gov* was developed. The NIA code does not specifically identify emergency funds obligated under a contract action. In fact, a contract action identified with an NIA code may contain both COVID-19- and non-COVID-19-related requirements and funds, making them less transparent to the Congress and the American people than the information available on *USASpending.gov* that uses the DEFC.

Question. In April 2019, GAO recommended that the Memorandum of Agreement between DHS, DOD, and GSA about the National Interest Action code be revisited to assess the extent to which the criteria for closing National Interest Action codes meet long-term visibility needs for high visibility events and account for the needs of users, such as FEMA, other agencies, and the Congress. To date, that recommendation is still open. Has DHS, in coordination with DoD and GSA, done such an assessment?

Answer. DHS, DoD, and the General Services Administration review the NIA Code Memorandum of Agreement (MOA) annually in keeping with project management best practices. The Government Accountability Office (GAO) recommendation under GAO-19-281 entitled “Disaster Contracting: Actions Needed to Improve the Use of Post-Disaster Contracts to Support Response and Recovery,” suggested that the MOA agencies consider the visibility needs for high visibility events and account for the needs of users, such as FEMA, other agencies, and the Congress when reviewing the MOA criteria. In response to that recommendation the MOA agencies revised the MOA criteria in 2019 to clarify that an NIA code would be closed if there was a consistent decline in the number of contract actions reported using the NIA designator. The visibility of information is a consideration of the MOA agencies in each annual review of the NIA criteria.

FEMA WORKFORCE SHORTAGES

Question. GAO’s prior work has identified acquisition workforce shortages at FEMA, particularly at FEMA’s regional offices, which have been involved in communicating information and responding to questions from State and local governments during the response to COVID-19.

What challenges have these workforce shortages posed for FEMA’s ability to procure medical and testing equipment and supplies in response to COVID-19?

Answer. FEMA’s staffing limitations did not adversely impact FEMA’s ability to procure medical and testing equipment and supplies in response to COVID-19 and the specific workforce challenges discussed in the question are not associated with FEMA’s contracting workforce. The CPO monitors and assists the Head of FEMA’s contracting activity in achieving and maintaining the required number of fully trained contracting professionals. Although FEMA’s vacancy rate has fluctuated, as of August 1, 2020, FEMA had a 7.1-percent vacancy rate in the contracting career field. FEMA uses all available hiring authorities and flexibilities to recruit sufficient numbers of highly skilled contracting professionals.

Question. Has FEMA taken steps to assess its acquisition workforce and develop a plan, including timelines, to address any gaps, as GAO recommended in April 2019?

Answer. The gaps that the GAO identified in FEMA’s workforce do not pertain to contracting personnel. The specific steps that FEMA has taken to assess its non-contracting positions within the acquisition workforce and develop a plan including timelines to address any gaps is outside the CPO’s purview.

QUESTIONS SUBMITTED BY HON. DEBBIE STABENOW

FILLAKIT CONTRACT

Question. In response to one of my questions, you stated that when entering into a contract with Fillakit, FEMA relied on an emergency use authorization provided to Fillakit by the Food and Drug Administration (FDA).

FDA has stated that there was no emergency use authorization awarded to Fillakit and that your statements to the record were therefore inaccurate.

Please respond to the following: please provide an explanation for the discrepancy between your statements on the record and FDA's assertion that Fillakit did not have an emergency use authorization, and that the FDA was not involved in the contracting process.

Answer. The CPO was provided erroneous information regarding the contract award to Fillakit. Unfortunately, the DHS Office of the Inspector General (OIG) has asked that specific information not be provided and instead this and all questions regarding Fillakit be referred to the DHS OIG for an accurate and complete response.

Question. Please provide a revised and corrected response to the request that you detail the criteria for awarding sole-source contracts and what steps were taken by FEMA to verify the accuracy of any representations or assurances made by Fillakit.

Answer. All questions regarding Fillakit should be referred to the DHS OIG so they can provide an accurate and complete response.

FILLAKIT CONTRACT LETTER

Question. On July 6, 2020, Secretary Azar and Administrator Gaynor received a letter from Senators Stabenow and Peters requesting information regarding the Fillakit contract. They have yet to receive a response.

Please provide an explanation for this lack of responsiveness.

Answer. All questions regarding Fillakit should be referred to the DHS OIG so they can provide an accurate and complete response.

UNSUITABLE TESTING SUPPLIES

Question. Please provide responses to the following: which States have received testing supplies purchased by FEMA and HHS that have subsequently been determined to be unsuitable, including those provided by Fillakit? Please provide a summary of the nature and quantity of the unsuitable supplies received by each State.

Answer. All questions regarding Fillakit should be referred to the DHS OIG so they can provide an accurate and complete response.

TESTING SUPPLIES

Question. What steps are FEMA and HHS taking to ensure that any States, including Michigan, that have received COVID-19 testing supplies will receive the supplies needed to continue testing at adequate levels? When can States expect to receive those supplies?

Answer. As of July 13, 2020, the Department of Health and Human Services (HHS) took over the distribution of testing supplies nationwide. DHS respectfully defers to HHS on the timeline for the distribution of testing supplies.

ESTIMATED TESTS

Question. What is the estimated number of COVID-19 tests in the United States that have been administered with supplies purchased from Fillakit?

What is the estimated number of COVID-19 tests that States have been unable to perform due to lack of supplies since FEMA and HHS issued guidance against using Fillakit supplies on June 20, 2020?

Answer. All questions regarding Fillakit should be referred to the DHS OIG so they can provide an accurate and complete response.

FILLAKIT CONTRACT AND STATEMENTS

Question. Please provide us with copies of any contracts between FEMA or HHS and Fillakit.

Please provide us with copies of any contractor assurance statements provided to FEMA or HHS by Fillakit.

Answer. The DHS OIG has respectfully requested that this and all questions regarding Fillakit be referred to the DHS OIG so they can provide an accurate and complete response.

VERIFY STATEMENTS

Question. What steps were taken by FEMA or HHS during the contracting process to verify the accuracy of any representations or assurances made by Fillakit?

Answer. All questions regarding Fillakit should be referred to the DHS OIG so they can provide an accurate and complete response.

FEMA POSITION

Question. Is it the position of FEMA or HHS that Fillakit is in breach of contract? If so, what steps are being taken to hold it liable? If not, why not?

Answer. All questions regarding Fillakit should be referred to the DHS OIG so they can provide an accurate and complete response.

CONTROLS IN PLACE

Question. What controls do FEMA or HHS have in place to ensure that other entities that have been awarded contracts to provide COVID-19 testing supplies are in fact providing supplies fit for COVID-19 testing purposes?

Answer. FEMA received guidance from HHS on the requirements of the testing products, to include requirements put forth from the CDC. The contract states the requirement for sterility in the supplies; as this is a commercially available item. Therefore, FEMA relies on the subject matter experts with the requirement [program office], receiving the deliverables, to conduct an inspection as best it can, using the guidelines it received from HHS/CDC.

In addition, as of July 2020, FEMA and all DHS Components are required to include the Component medical officer as part of the decision-making team when selecting the testing processes and supplies for internal use, to ensure that the appropriate testing supplies are procured.

QUESTIONS SUBMITTED BY HON. ROBERT MENENDEZ

FEMA'S PROCEDURES

Question. In April of this year, FEMA awarded Panthera Worldwide a \$55-million procurement contract for 10 million N95 protective masks. The company failed to deliver the equipment on time and the contract was canceled. The company had never manufactured N95 masks nor had they previously distributed medical equipment.

Please provide this committee information on FEMA's procedures when awarding large disaster contracts for delivery of critical goods.

Answer. FEMA awards all contracts in accordance with the FAR, and applicable agency supplements. FEMA generally uses full and open competition in accordance with the FAR to award multiple commercial contracts or agreements for critical disaster response or recovery items. For instance, FEMA has multiple award blanket purchasing agreements for bottled water and meals. These large contracts or agreements for routine emergency response and recovery items are negotiated well in advance of the need and include a process to quickly compete orders among the approved providers to ensure prompt delivery at a fair and reasonable price.

In accordance with FAR subpart 9.103, the CO must make an affirmative determination of responsibility before award, and that responsibility must reflect the requirements of the proposal. To be determined responsible, a prospective contractor must satisfy the following requirements: ability to comply with schedule, satisfactory performance record, and satisfactory integrity and ethics. The award process includes reviewing the contractor's proposal in concert with review of Federal Awardee Performance and Integrity Information System (FAPIIS); Contractor Performance Assessment Reporting System; and System Award Management (*SAM.gov*) to assess the contractor's technical, financial and performance capability.

Question. Were FEMA's contracting procedures followed in the awarding of the contract to Panthera Worldwide?

Answer. Yes, FEMA followed all laws, regulations and DHS policies when awarding the Panthera contract.

FEMA AWARDING

Question. Why did FEMA sign a high-dollar contract with a company that is not a trusted medical manufacturer or distributor?

Answer. No purchase or award is made unless the prospective awardee is determined to be a responsible contractor in accordance with the requirements of Federal Acquisition Regulation subpart 9.1, Responsible Prospective Contractors. The review of the company and its proposal lead FEMA to conclude the offeror would be able to fulfill the contract. In addition, the CO performed a contractor responsibility determination in accordance with FAR part 9 and found the contractor responsible.

On the day of award to Panthera Worldwide, the CO reviewed records from FAPIIS, and the Excluded Parties List System, now included as part of *SAM.gov*. These databases assist Government Contracting Offices with determining if the contractors have, within the last 5 years, been the subject of a criminal, civil and/or administrative proceeding at the Federal or State level in connection with a Federal award that resulted in a conviction or finding of fault or liability. They also provide information on Suspensions, Debarments, and active exclusions. When vendors register in *SAM.gov*, they have to provide their Taxpayer Identification Number, and the Federal Government reviews all tax documents before they are approved and become active in *SAM.gov* to accept a government contract. Vendors are required to re-apply with *SAM.gov* every 12 months. The CO verified all representations and certifications were current, accurate, and complete; and ensured no exclusion existed for the awardee in *SAM.gov*. Therefore, there was no information that would have precluded Panthera from receiving an award.

PANTHERA WORLDWIDE CANCELLATION

Question. Please provide this committee information on what happened with FEMA and Panthera Worldwide that led to the cancellation of the contract.

Answer. Panthera failed to deliver the items ordered by the required date, and that failure to deliver resulted in termination of the contract. Panthera received no payments under this contract.

INVESTING IN DOMESTIC MANUFACTURERS

Question. As Chief Procurement Officer at DHS, what steps has your office taken to identify and invest in domestic manufacturers who are known and trusted suppliers of PPE to help them ramp up production and meet demand?

Answer. DHS supports domestic manufacturers and procures PPE from these sources when it is available to meet DHS needs. In doing so, DHS adheres to FAR part 25, Foreign Acquisition, which details the application of the BAA and Trade Agreements Act (TAA), including the dollar thresholds at which the TAA supersedes the BAA and when nondomestic trading partners receive equal treatment with domestic sources. DHS has a supplement to the FAR, known as the Homeland Security Acquisition Regulation (HSAR), which addresses statutes and other matters unique to DHS, such as the Kissell Amendment. The HSAM—DHS's internal acquisition policies and procedures—implements or supplements requirements of the FAR and HSAR.

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN

MOVING SUPPLY CHAINS

Question. In Maryland and across the country, shortages of PPE have crippled our ability to protect our front-line workers from COVID-19. Though they have taken piecemeal actions, there has been a complete and total absence of a national plan from the Trump administration to address PPE shortages. The result has been States, localities, health-care systems, and other industries deemed essential fending for themselves and competing against one another to procure PPE.

The Trump administration could have taken numerous actions to increase the supply of PPE, including fully utilizing the Defense Production Act. Had the Trump

administration used the DPA, we might have developed better domestic capabilities to address PPE supply shortages. In lieu of substantive action or direction by this administration, I am curious to hear the panel's thoughts on actions the private sector is taking on their own initiative.

What are the plans to move portions of supply chains in-country in order to protect against reliance on foreign country resources?

Answer. Effective use of the Defense Production Act (DPA) and other authorities such as the CARES Act have allowed the United States to grow the domestic industrial base to meet the increased demands associated with operating in a COVID-19 environment. We are now starting to see these actions result in increased production capacity. As stated earlier, domestic production of N95 masks is well underway. Growth in glove, gown, and surgical mask production is also gaining momentum. In addition, the USG is pursuing efforts to now on-shore critical pharmaceuticals.

To date, we are witnessing increased procurement of PPE substantially from domestic and international sources and steps are being made to increase domestic manufacturing capabilities and capacity to reduce the reliance on foreign markets. Already, a robust U.S. oil refining industry is meeting domestic demand, as well as, a substantial overseas demand for polypropylene. Through various partnerships, the Federal Government and domestic manufacturers are expanding the capability to conduct more on-shore extrusion to increase domestic poly-fabric production. To further aid our domestic manufacturing industry and overcome immediate shortages and meet future demand, FEMA, HHS and DoD used DPA authorities to ensure prioritization of Federal contracts on PPE production lines and to expand domestic production capacity for melt-blown fiber/filter media. The joint government team let industrial base expansion contracts to offset foreign market risk associated with manufacture of poly-fabrics, and ultimately final assembly of PPE.

RAMPING UP PRODUCTION

Question. What are suppliers doing to ramp up production now to minimize need for allocations to hospitals?

Answer. Effective use of the DPA and other authorities such as the CARES Act have allowed the United States to grow the domestic industrial base to meet the increased demands associated with operating in a COVID-19 environment. We are now starting to see these actions result in increased production capacity. As stated earlier, domestic production of N95 masks is well underway. Growth in glove, gown, and surgical mask production is also gaining momentum. In addition, the U.S. Government is pursuing efforts to now on-shore critical pharmaceuticals.

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DEFECTIVE PPE

Question. Maryland health providers have been fortunate to not have received exceptional amounts of counterfeit personal protective equipment like some other States. However, some of our long-term health facilities reported that they received an order of 6,000 medical gowns that were counterfeit. This senior care provider association returned the counterfeit gowns to the vendor and refused delivery of a subsequent order.

This same senior care provider association also reported that many Maryland long-term care facilities received gowns from FEMA that were not usable as effective personal protective equipment as they were actual bags with holes cut out for a head.

When a health provider receives a shipment of defective PPE from the Federal Government, for example FEMA, who should they report the issue to?

Answer. The health provider should report any shipment of defective PPE to the U.S. Food and Drug Administration (FDA), as well as the department or agency from which it was received. If received from FEMA, it should be reported to the State's respective FEMA Region.

Question. What steps does FEMA take to ensure the recipient receives a quality product in the Federal PPE shipments?

Answer. If FEMA procures PPE, FEMA will ensure that the contract cites the Federal regulation and the technical specification as required by the FDA.

LEAD ON HOARDING AND PRICE GOUGING

Question. On March 23, 2020, President Trump signed an executive order (EO 13910) to prevent hoarding of health and medical resources necessary to respond to COVID-19 within the United States. The order prohibits any person from accumulating designated materials such as personal protective equipment (1) in excess of the reasonable demands of business, personal, or home consumption or (2) for the purpose of resale at prices in excess of prevailing market prices.

This April, there were reports that the Department of Justice (DOJ) and the Department of Health and Human Services (HHS) seized hundreds of thousands of N95 respirators, gloves, and surgical masks from a New York City man allegedly hoarding these supplies. However, when my office reached out to both DOJ and HHS for an update on enforcement actions and policy guidance, my staff was told that the Department of Homeland Security (DHS) was now the agency in charge of enforcement and policy guidance for this executive order.

Has DHS been officially designated the lead on this executive order to prevent hoarding and price gouging?

Answer. No, DHS has not been officially designated the lead on this executive order to prevent hoarding and price gouging.

ENFORCEMENT ACTIONS

Question. Is DHS working with HHS to release additional policy guidance on the executive order in regards to what constitutes hoarding and price gouging in excess of the prevailing market price?

What enforcement actions to date has DHS taken to ensure that people are not hoarding materials or price gouging our health system, health providers, and State and local governments?

Answer. No additional administrative materials are being collaborated on at this time.

Question. What enforcement actions to date has DHS taken to ensure that people are not hoarding materials or price gouging our health system, health providers, and State and local governments?

Answer. As DHS has not been officially designated the lead on the executive order to prevent hoarding and price gouging, DHS has not taken any enforcement actions for such cases against any health system, health providers, or State and local government.

The Department of Justice has assembled a COVID-19 Hoarding and Price Gouging task force to identify cases of price gouging and may alert FEMA to some shipments and stockpiles of PPE. Under DPA authorities, FEMA may then compel a price gouger to sell PPE in its control to FEMA at prevailing market prices, not gouging prices.

SECURE THE SUPPLY CHAIN

Question. Throughout this COVID-19 pandemic, many State and local health departments and health providers have felt at the mercy of a wholly inadequate medical supply chain. During March, April, and May, my office fielded calls from local health departments and providers who were unable to obtain sufficient personal protective equipment for their staff.

Fortunately, the Maryland Hospital Association and the Maryland Department of Health have worked closely together to ensure our State has adequate PPE throughout the fall. However, nursing homes, home health providers, and other essential

health workers still struggle to find PPE. We must have sufficient PPE for our frontline workers in order to successfully overcome this public health crisis.

What steps is your agency and/or department taking to secure the U.S. medical supply chain as we go into the fall?

Answer. Under title VII of the DPA, FEMA formed the “Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic” to facilitate collaboration with the private sector during a pandemic. This agreement is valid for 5 years and will assist with the ongoing response to the COVID–19 pandemic and any future events.

Additionally, FEMA published a Temporary Final Rule (TFR) in the Federal Register on August 10, 2020 allocating certain health and medical resources for domestic use during the COVID–19 pandemic. This TFR is an extension and modification of a TFR published on April 10, 2020 which outlined the implementation of the President’s Memorandum, “Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use.” This extension allows the TFR to remain in effect, with certain modifications, through December 31, 2020. FEMA published a Fact Sheet to answer questions about the TFR, its exemptions, and its implementation.

DHS Office of the Chief Information Officer (OCIO) Cybersecurity Supply Chain Risk Management (SCRM) Program is currently responsible for the evaluation of DHS’s internal Information and Communications Technology (ICT) use for the Department. This evaluation would encompass an ICT SCRM review of medical ICT should DHS purchase/use, but not specifically end products such as “test tubes.” For example, this type of fraudulent activity may be best evaluated by the DHS OIG Investigations office. Their role is to look into fraudulent aspects related to the subject of this request.

DHS OCIO continues to work with OCPO to address risk as we procure the appropriate future medical supplies to meet departmental needs.

Question. Do you need additional authorities from Congress to secure the supply chain? If so, what authority do you need?

Answer. Securing the supply chain is an ongoing priority for the Department. The Chief Information Officer and the Chief Information Security Officer are assessing authorities the Department may need. To date, they have not identified any specific authorities the Department immediately needs to implement its SCRM process.

DISTRIBUTION CHALLENGES

Question. What challenges have you faced and continue to face in obtaining PPE and distributing it to State and local governments?

Answer. DHS does not procure PPE for distribution to State and local governments at this time. FEMA received a delegation from HHS pursuant to the Stafford Act to obtain and assist HHS in distributing PPE in March 2020. This delegation was transferred to DLA effective June 5, 2020. DLA has not advised my office that they are currently experiencing any issues obtaining PPE or distributing it to State and local governments. However, DHS respectfully defers you to DLA for additional information on this matter.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

RIOT PERSONNEL

Question. The Department of Homeland Security’s presence at demonstrations for racial justice has been well-documented at multiple cities across the country.

Please identify the DHS personnel that were dispatched to respond to demonstrations for racial justice, including the number of personnel, the rank of personnel, and the DHS department from which the personnel were dispatched.

Answer. The Department provided robust support to our State and local law enforcement partners due to the civil unrest after the death of Mr. George Floyd. This has included standing up the Protecting American Communities Task Force to ensure that iconic monuments and Federal property are protected. Over the 4th of July weekend, the following entities deployed law enforcement officers to protect iconic property:

- Federal Protective Service (FPS): 97.
- CBP: 58.
- U.S. Immigration and Customs Enforcement (ICE): 38.
- Transportation Security Administration (TSA): 18.
- U.S. Secret Service: 3.

Over the 4th of July weekend, the Department deployed to Washington, DC, Pennsylvania, Virginia, Oregon, Maryland, and the State of Washington.

Additionally, the Department has a continued presence in Portland, Oregon to protect Federal property against violent opportunists. As of August 25, the following DHS entities were deployed:

- FPS: 91.
- CBP: 62.
- ICE: 47.
- DHS Office of Intelligence and Analysis: 2.

Question. Please identify the individual responsible for making the decision to dispatch DHS personnel to respond to demonstrations for racial justice.

Answer. The Department’s leadership provides overall direction for deployment due to civil unrest. The Office of Operations Coordination facilitates coordination and synchronization between Components and the interagency to ensure efficient and effective deployment. Each of the Department’s Operational Components has its own respective command and control structure to ensure appropriate deployment for respective missions.

RIOT EQUIPMENT

Question. Please identify the equipment or vehicles that were deployed to communities in response to demonstrations for racial justice. Please provide details on the use of that equipment at each location to which it was deployed, including whether any of the equipment was involved in any interactions with demonstrators that resulted in injury or casualty.

Answer. The Department deployed in multiple cities across the United States to protect American communities. This included the deployment of personnel and assets.

USE OF FORCE INVESTIGATIONS

Question. Were any DHS personnel involved in any interactions with demonstrators that resulted in injury or casualties?

Answer.

	Federal LEO Injuries	State/Local/Tribal LEO Injuries
May/June nationwide civil unrest	147	930
Portland ¹	343	21

¹ As of August 25, 2020.

Additionally, one FPS officer was shot and killed protecting Federal property in Oakland, CA. We honor the life and legacy of Officer Patrick Underwood, his family, and the men and women of FPS that sacrifice their safety to protect Federal employees and our homeland.

Question. Please provide details for each interaction that resulted in injury or casualty, including the status of an investigation by DHS and any other agency into the interaction.

Have any DHS personnel been reprimanded for use of excessive force or other infractions committed during their deployment in response to demonstrations for social justice?

Please provide details on the number of personnel, the infractions for which the personnel were cited, and the actions taken against personnel who were cited.

Answer. The Department cannot provide a written response due to pending investigations, including those being conducted by the OIG.

GRANT PROGRAMS

Question. Please identify the grant programs through which States and localities can fund purchases of equipment or vehicles for law enforcement use.

Answer. While there is no DHS program that is dedicated or specific for this purpose, there are a few FEMA-administered grant programs that allow the purchase of equipment or vehicles for law enforcement (LE) use:

- Homeland Security Grant Program (HSGP) (includes the State Homeland Security Program, Urban Area Security Initiative, and Operation Stonegarden): Recipients (*e.g.*, the State Administrative Agency) and subrecipients are permitted to purchase LE equipment or vehicles, subject to statutory and regulatory requirements and limitations in the applicable Notice of Funding Opportunity, the Preparedness Grants Manual, and the Authorized Equipment List.
- Port Security Grant Program (PSGP): Recipients are permitted to purchase LE equipment or vehicles, subject to statutory and regulatory requirements and limitations in the applicable Notice of Funding Opportunity, the Preparedness Grants Manual, and the Authorized Equipment List.
- Transit Security Grant Program (TSGP): Recipients and subrecipients are permitted to purchase LE equipment or vehicles, subject to statutory and regulatory requirements and limitations in the applicable Notice of Funding Opportunity, the Preparedness Grants Manual, and the Authorized Equipment List.
- Tribal Homeland Security Grant Program (THSGP): Recipients and subrecipients are permitted to purchase LE equipment or vehicles, subject to statutory and regulatory requirements and limitations in the applicable Notice of Funding Opportunity, the Preparedness Grants Manual, and the Authorized Equipment List.

Additionally, FEMA Information Bulletin (IB) 426 (*Guidance to Recipients and Subrecipients of FEMA Preparedness Grants Regarding Implementation of Executive Order 13809 Restoring State, Tribal, and Local Law Enforcement's Access to Life-Saving Equipment and Resources*, November 1, 2017) reinforces that grant funds may not be used for the purchase of equipment not approved by DHS/FEMA, and lists specifically prohibited items including:

- Weapons and weapons accessories.
- Firearms.
- Ammunition.
- Grenade launchers.
- Bayonets.
- Weaponized aircraft, vessels, or vehicles of any kind with weapons installed.

As further detailed in IB 426, equipment intended to be used for riot suppression including riot batons, riot helmets, and riot shields are an unallowable expense under any FEMA preparedness grant program.

Question. Please identify whether any equipment or vehicles used by State or local law enforcement to respond to demonstrations for social justice were funded through a DHS grant program. Please provide the specific equipment, the State or locality that purchased it through a DHS grant program, and the grant program that provided funding for the equipment or vehicles.

Answer. The purpose of PSGP is to implement Area Maritime Transportation Security Plans and facility security plans, so any requests for funding must be used to correct U.S. Coast Guard-identified port vulnerabilities and ensure compliance with the security plans per 46 U.S.C. § 70107. The purpose of TSGP is to fund security improvements for public transportation agencies, and all requests for funding must be used to address items included in a security assessment or further a security plan per 6 U.S.C. § 1135. Any and all purchases must comply with applicable statutory and regulatory requirements, as well as limitations in the applicable Notice of Funding Opportunity, the Preparedness Grants Manual, and the Authorized Equipment List.

Additionally, and as noted in the previous response, equipment intended to be used for riot suppression including riot batons, riot helmets, and riot shields are an unallowable expense under any FEMA preparedness grant program. While it is possible that allowable equipment or vehicles that were purchased using FEMA-administered grant funding were used in response to demonstrations or civil unrest, FEMA is not aware of any such instances.

Question. Please also indicate whether any DHS-funded equipment or vehicle was involved in any interactions with demonstrators that resulted in injury or casualty.

Please provide details on each interaction in which DHS-funded equipment was used and resulted in injury or casualty.

Answer. We are unaware if any DHS-funded equipment or vehicles were involved in any interactions with demonstrators that resulted in injury or casualty. In addition, DHS grant funding is not tracked to specific equipment or vehicles.

CBP SPENDING

Question. Last year, multiple children died in CBP custody and CBP claimed they didn't have enough resources to provide adequate medical care to the families who were arriving at the southern border. In response, Congress provided emergency funding and appropriated funding specifically for humanitarian needs and yet instead of spending money on medical care, food, and clothing, like we instructed, CBP bought dirt bikes and ATVs, upgraded their computers, purchased supplies for their canine program, and fixed their sewer system. In response to this, the GAO issued a legal decision in June finding that this spending was very likely illegal, as a violation of the Antideficiency Act.

As the Chief Procurement Officer for the Department, can you explain this complete mismanagement of funds? If Congress instructs that money be spent on "consumables and medical care," why would CBP think it's okay to spend that money on ATVs?

In light of this GAO decision, is DHS making any changes to its procurement processes to make sure this does not happen again?

Answer. Although the GAO stated that CBP obligated some appropriated funds for purposes other than consumables and medical care, it is important to note that: (1) all obligations were for lawfully authorized consumable goods and services, such as food and hygiene products, as well as medical care goods and services including defibrillators, masks, and gloves needed to accomplish CBP's mission and agency operations in the midst of an unprecedented humanitarian crisis; and (2) only a very small percentage of these obligations were inaccurately categorized.

Specifically, in response to GAO's legal opinion, CBP counsel and others carefully reviewed all obligations and determined that the majority—including the vehicle purchases—were, in fact, properly charged. In addition, a CBP Office of Finance analysis determined that these obligations only represented 0.35 percent of the \$1.1B supplemental bill, and \$3.9M (or 3.48 percent) of the total \$112M consumables and medical care line item. CBP is in the process of remedying the categorization of the transactions by making the appropriate accounting adjustments and has already taken steps to see that the remaining 2019 emergency supplemental appropriations act expenditures are charged appropriately in the first instance. CBP takes the need to safeguard taxpayer dollars appropriated by Congress very seriously and is committed to accurately recording all of its obligations.

Question. Does DHS have any systems in place to ensure that when Congress appropriates money for a specific purpose, the money is actually spent that way?

Answer. DHS follows the budget execution and management control regulations found in the Office of Management and Budget (OMB) Circular A-11 as well as section 2.4 of the DHS Financial Management Policy Manual, "Budget Execution," which supplements the OMB guidance. The purpose of section 2.4 is to ensure that budgeted resources are used properly and accounted for consistently during the execution process, in full compliance with the Anti-Deficiency Act (ADA) (Pub. L. 97-258, as amended). Further, DHS requires resource managers to complete an ADA training course every 2 years. Newly hired resource managers have 60 calendar days from the entry-on-duty date to complete their initial training.

Question. In light of this GAO decision, is DHS making any changes to its procurement processes to make sure this does not happen again?

Answer. No, the OCPO already trains all DHS contracting professionals on appropriations law principles. A representative from the Chief Financial Officer's Office reviews each procurement and certifies that the type of funding is appropriate for the procurement in accordance with appropriations law, regulation and DHS policy before the contracting officer is authorized to sign the contract.

PREPARED STATEMENT OF STEVE FRANCIS, ASSISTANT DIRECTOR, GLOBAL TRADE INVESTIGATIONS DIVISION; AND DIRECTOR, NATIONAL INTELLECTUAL PROPERTY RIGHTS COORDINATION CENTER, IMMIGRATION AND CUSTOMS ENFORCEMENT, DEPARTMENT OF HOMELAND SECURITY

INTRODUCTION

Chairman Grassley, Ranking Member Wyden, and distinguished members of the committee, thank you for the opportunity to testify before the committee on U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations' (HSI) response to those exploiting the Coronavirus Disease 2019 (COVID-19) pandemic.

As the largest investigative agency within the U.S. Department of Homeland Security (DHS), HSI investigates and enforces more than 400 Federal criminal statutes, including the U.S. customs laws under title 19 of the United States Code, and general Federal crimes under title 18 of the United States Code, as well as many others. HSI Special Agents use this unique and broad statutory authority to investigate all types of cross-border criminal activity and work in close coordination with our Federal, State, local, tribal, and international partners in a unified effort to target those nefarious actors trying to capitalize on the COVID-19 pandemic through fraud.

COVID-19 is a worldwide pandemic affecting nearly every country in the world. Despite widespread illness and death caused by COVID-19, individuals and organizations operating around the globe are actively seeking to exploit the pandemic for illicit financial gain. The illicit schemes these entities employ compromise legitimate trade and financial systems, threaten the integrity of the U.S. border, and endanger the safety and security of the American public. In April 2020, HSI launched Operation Stolen Promise to utilize the agency's unique authorities, robust cyber capabilities, and strategic partnerships worldwide to protect the Homeland from the increasing and evolving threat posed by COVID-19-related fraud and criminal activity.

COVID-19-RELATED CRIMINAL ACTIVITY

As the COVID-19 pandemic has evolved and intensified, concerned Americans have sought to acquire test kits, personal protective equipment (PPE), medicines, hygiene products, and other medical equipment and supplies to protect themselves from the virus. Criminal networks and nefarious individuals worldwide are capitalizing on this sudden global demand, and are flooding the Internet with fraudulent, counterfeit, substandard, or unapproved products. Illicit websites are selling fake goods, defrauding consumers, degrading the integrity of legitimate commerce and trade, and endangering the lives of U.S. consumers. As new kits to test for COVID-19 and drugs to treat the virus have been developed and tested, criminal actors have shifted their operations accordingly; and they continue to sell counterfeit, unapproved, and substandard kits and pharmaceuticals, predominantly in online marketplaces.

Criminal organizations that historically have been engaged in financial scams such as bank and loan fraud, romance scams, Internal Revenue Service (IRS) scams, investment opportunity scams, and business email compromise are now pivoting to exploit this pandemic and associated lending opportunities and stimulus packages for illegal financial gains. At the same time, crimes of victimization continue to persist, with vulnerable populations being exploited by financial fraud schemes and offers of counterfeit, substandard, or non-existent PPE. As the pandemic has continued to take grip, financial fraud scams involving financial relief, paycheck protection program, and stimulus checks have also surged. In addition to the financial industry, these fraud scams also impact government public benefit agencies that are in the process of distributing aid and providing assistance.

HSI RESPONSE

Since March 2020, HSI offices domestically and internationally have seen a significant increase in COVID-related fraud and other criminal activity. In response, HSI has intensified collaboration and partnership with multiple Federal departments and agencies, along with business and industry representatives, to ensure the surging criminal activity surrounding the COVID-19 pandemic is met with an equally robust investigative response. Together, HSI and its partners are actively targeting those who attempt to sell counterfeit, substandard or otherwise unlawful pharmaceuticals and medical supplies and exploit this pandemic for illicit financial gain, as well as the platforms and Internet provider accounts enabling this illicit

activity. Additionally, HSI special agents are working alongside domestic and foreign law enforcement, regulatory agencies, financial institutions, and non-governmental organizations to identify and investigate COVID-19 related financial schemes targeting both the public and private sectors, to include government, businesses, and individuals. Taking a victim-centered approach, HSI endeavors to remedy, as much as possible, financial losses to individuals, businesses, and public and private institutions by ensuring that money acquired through fraud is returned to victims. As of July 24, 2020, HSI efforts have disrupted illicit transactions and recovered victims' funds of approximately \$17.9 million.

OPERATION STOLEN PROMISE OVERVIEW

In April 2020, HSI officially launched Operation Stolen Promise to protect the homeland from the increasing and evolving threat posed by COVID-19-related fraud and criminal activity. Operation Stolen Promise is a strategic plan which combines HSI's expertise in global trade, financial fraud, international operations and cybercrime to investigate financial fraud schemes, the importation of unlawful pharmaceuticals and medical supplies, websites defrauding consumers, and any other illicit criminal activities associated with the virus that compromises legitimate trade or financial systems and endangers the public.

Since the launch of this operation, HSI has opened over 570 investigations nationwide, seized over \$7 million in illicit proceeds, made 53 arrests, executed 75 search warrants, analyzed over 50,000 COVID-19-related domain names, and worked alongside U.S. Customs and Border Protection (CBP) to seize over 900 shipments of mislabeled, fraudulent, or unauthorized COVID-19 test kits, treatment kits, homeopathic remedies, purported anti-viral products, and PPE.

Operation Stolen Promise was built around four central pillars: partnership, investigation, disruption, and education. Each represents a core element of the HSI approach to addressing COVID-19 fraud. Since the operation's inception, HSI has implemented key actions under each of these pillars to take a comprehensive, multi-faceted approach to combatting COVID-19-related fraud across multiple fronts.

OPERATION STOLEN PROMISE CENTRAL PILLARS

Partnership

HSI, using its network of 80 Attaché offices in 50 countries, is partnering with both government and private-sector partners around the world to comprehensively and effectively prevent and investigate criminal activity surrounding the pandemic. Strong partnerships are critical to strengthening global supply-chain security and will ultimately protect the American public from victimization.

HSI works alongside CBP on a daily basis to identify and investigate the illegal import and export of unlawful pharmaceuticals and medical supplies. As of July 24, 2020, HSI and CBP have collaborated to seize over 900 shipments of mislabeled, fraudulent, or unauthorized COVID-19 test kits, treatment kits, homeopathic remedies, purported anti-viral products, and PPE.

HSI also works closely with the Food and Drug Administration (FDA), the IRS, the U.S. Postal Inspection Service (USPIS), the Small Business Administration (SBA), the Federal Bureau of Investigation, the Department of Justice (DOJ) Consumer Protection Branch, the DOJ Computer Crime and Intellectual Property Section, U.S. Attorney's Offices around the country, and other Federal, State, and local agencies to investigate and prosecute all forms of COVID-19-related fraud and criminal activity. These collaborative efforts span across multiple HSI components, including the National Intellectual Property Rights Coordination Center (IPR Center), the National Targeting Center—Investigations (NTC-I), the Illicit Finance and Proceeds and Crime Unit (IFPCU), the Cyber Crimes Center (C3), and HSI International Operations. The IPR Center also receives funding from the Department of State to deliver training and technical assistance to foreign law enforcement partners designed to strengthen their ability to cooperate with us.

With over 80 international offices in more than 50 countries, HSI has one of the largest international footprints in U.S. law enforcement. Positioned within embassies, consulates, and combatant commands around the world, HSI personnel abroad are leveraging relationships with other nations to exchange information and to jointly investigate illicit COVID-19 fraud schemes. On a daily basis, HSI special agents worldwide are engaging foreign law enforcement and customs partners to prevent shipments of unlawful pharmaceuticals and medical supplies from reaching the U.S., to disrupt or dismantle illegal supply networks at the point of origin, to thwart

illicit financial fraud as it occurs, and to assist in repatriating funds to victims. To date, the Five Eyes Law Enforcement Working Group has been a core component to HSI's international efforts on Operation Stolen Promise.

The HSI-led IPR Center, which stands at the forefront of the United States Government's response to combating global intellectual property (IP) theft and enforcing international trade laws, is working with its 25 Federal and industry partners to identify, interdict, and investigate individuals, companies, and criminal organizations engaging in the illegal importation of COVID-19-related products. As part of this effort, on May 5, 2020, industry leaders from Pfizer, 3M, Citi, Alibaba, Amazon, and Merck announced that they joined forces with the IPR Center in an unprecedented public-private partnership to combat fraud and other illegal activity surrounding COVID-19. Additionally, HSI is working closely with banks, money services businesses, and other financial institutions to identify, target, and disrupt COVID-19 financial fraud schemes, and is leveraging its partnerships with the cyber security industry and its cyber threat intelligence capabilities to identify and take down websites being utilized to facilitate COVID-19-related fraud and criminal activity.

Investigation

HSI and its partners are developing and pursuing actionable intelligence and investigative leads into those criminally exploiting the pandemic. These efforts are led by HSI special agents in domestic and international field offices and are being spearheaded by HSI's IPR Center, NTC-I, C3, and IFPCU. Investigative efforts center on global trade investigations, financial investigations, and cyber investigations.

The IPR Center and the NTC-I lead the U.S. government's response to combating global IP theft and enforcement of its international trade laws and serve as the primary HSI entities for the exchange of information and intelligence related to COVID-19 illicit criminal activity. Through established relationships with government and private-sector partners, the IPR Center and NTC-I are spearheading efforts to identify, interdict, and investigate individuals, companies, and criminal organizations engaging in the illegal importation of COVID-19-related pharmaceuticals and medical items, such as test kits and PPE.

HSI's investigative efforts pursuant to Operation Stolen Promise have revealed that the degree of fraud being perpetrated is representative of the panic resulting from the pandemic. As information on potential cures, tests, PPE, etc., spreads to the public, the types of fraud quickly change to meet these perceived new needs. This was true, for example, with hydroxychloroquine.

Many of the items detained by CBP and HSI have not been approved or otherwise authorized by the FDA or the Environmental Protection Agency. Unfortunately, consumers have no way to know if these items are in fact legitimate or if they will work if ordered from third-party marketplaces or non-medical websites. Based on the seizures made in conjunction with HSI's partners at CBP, approximately 56 percent of seizures originate in China and Hong Kong. The largest percentage of seizures have been COVID test kits at 45 percent, followed by pharmaceuticals at 27 percent, viral lanyards at 16 percent, and PPE at 10 percent. While all products are not necessarily counterfeit, they may not meet U.S. regulatory standards nor provide the medical benefits they claim. To date, HSI has seen a substantial number of inbound COVID-19 test kits going to residential addresses. Acting upon information obtained through CBP seizures, HSI has leveraged our longstanding relationships with foreign customs and law enforcement officials to provide actionable intelligence which has resulted in arrest and seizures overseas. These arrests and seizures have prevented substandard and unregulated pharmaceuticals, PPE, and test kits from entering the domestic medical supply chain.

Since the launch of Operation Stolen Promise, the HSI IFPCU has worked closely with HSI field offices around the world and with its key partners to initiate, pursue, and support HSI investigations related to COVID-19 fraud. HSI has seen that scammers have attempted to profit from the pandemic through a number of means, including bank and loan fraud, fraudulent fundraising for fake charities, various medical scams and online sales of counterfeit medicines, medical supplies, testing kits, and PPE. Additionally, HSI has directed agents to pursue criminals who are engaged in crimes of victimization, with a particular focus on those who exploit vulnerable populations including the elderly.

To date, reporting from HSI domestic and international field offices and from the Federal Trade Commission all suggest that previously existing online fraud schemes and mass marketing scams have pivoted to exploit the COVID-19 pandemic. HSI

is working closely with numerous Federal agencies including the DOJ, IRS, USPIS, the Treasury Inspector General for Tax Administration, and the SBA Office of the Inspector General to analyze data associated with individuals and businesses attempting to exploit the economic stimulus package and defraud the United States Government.

Through an HSI-led COVID-19 Virtual Task Force, respective agencies provide guidance and direction to field agents to collaborate with members in order to identify vulnerabilities and provide resources and expertise to effectively combat illicit actors engaged in financial fraud activities. HSI has integrated its Office of Intelligence and Innovation Lab into this effort to support ongoing activities by HSI and its partners to research and track investigative leads related to COVID-19 fraud. These leads are being sent to HSI field offices and to the COVID-19 Fraud Task Force partners for further investigation. As of July 24, 2020, Operation Stolen Promise has led to the seizure of over \$2.2 million related to CARES Act fraud.

The HSI C3 and its cybersecurity partners have continued to use the full extent of their investigative, analytical, and technical resources to collaboratively process and enrich data to target individuals and criminal organizations attempting to exploit this pandemic for illegal financial gains via fraudulent schemes. As Operation Stolen Promise has unfolded, C3 has committed to increasing enforcement by targeting online platforms and dark web sites enabling the sale and distribution of illicit materials related to COVID-19 and victimizing the American people. In addition to investigating the criminal elements operating illegally on the web, C3 has achieved significant success within the third pillar of Operation Stolen Promise, disruption. These efforts will be further described soon.

Disruption

Since launching Operation Stolen Promise, HSI has utilized the full breadth of its authorities to disrupt and dismantle fraud schemes; takedown illicit websites and other illegal online marketplaces; seize counterfeit or illicit pharmaceuticals and medical devices; and arrest and dismantle the organizations responsible. As of July 24, 2020, HSI special agents have seized over \$7 million in illicit proceeds, made 53 arrests, executed 75 search warrants, conducted 42 disruptions of potential criminal activity, took appropriate disruption activity on thousands of illicit websites, and seized over 900 shipments of unlawful pharmaceuticals or medical supplies. Furthermore, HSI disrupted the flow and blocked the transfer of approximately \$18 million being sent to fraudulent entities which were offering goods, services, or financial support under the guise of COVID-19 relief, protecting those consumers who were being defrauded.

A key element to HSI's disruption activities under Operation Stolen Promise are C3's efforts in the cyber realm. C3 leads the agency's response to preventing transnational criminal organizations, nefarious individuals, and malicious actors from exploiting this pandemic through online fraudulent schemes and the sale and distribution of illicit COVID-19 materials through nefarious online markets and the dark net.

Pursuant to Operation Stolen Promise, C3 has partnered with public/private and cybersecurity partners as well as other Federal law enforcement agencies to identify and analyze fraudulent websites, social media platforms and other online forums responsible for the advertisement of illicit COVID-19-related material. C3 and HSI special agents in the field work with website hosts and U.S. registrars to disrupt these illicit sites and to prevent the flow of dangerous items as quickly as possible, while still maintaining evidence for potential criminal investigation and prosecution. Once a suspected fraudulent domain is identified, it is referred to a field office for criminal investigation or referred to Internet governance partners for appropriate action.

To date, C3 has analyzed over 50,000 COVID-19 suspected fraudulent domains for appropriate disruption action. These included phishing websites impersonating legitimate businesses selling COVID-19 supplies and charitable organizations conducting COVID-19 fundraising. Additional websites have been set up for the purpose of executing malware and for selling COVID-19-related supplies that the sellers never intend on sending to the customer.

Education

One of the main goals of Operation Stolen Promise is to educate the public on the various types of fraudulent activity associated with the pandemic. To that end, HSI launched a robust public awareness campaign—S.T.O.P. COVID-19 Fraud—to relay critical information to the public on COVID-19 fraud and criminal activity.

Through this initiative, HSI is able to provide facts, tips, and red flags on pandemic-related crime and to guide the public on how to recognize potential fraud, protect themselves from it, and report it to authorities. HSI has developed outreach materials specifically for this effort, which are posted online in English and Spanish, and are available for HSI personnel to share with both public and private sector partners at meetings and other outreach events.

Additionally, HSI launched a dedicated COVID-19 webpage on *ICE.GOV* to provide information to the public on COVID-19-related fraud schemes. The page highlights the investigative efforts the agency is taking to counter the threats posed by individuals and criminal organizations seeking to exploit the pandemic for illicit financial gain and what HSI and its partners are doing to protect the public during the COVID-19 pandemic. HSI's S.T.O.P. COVID-19 Fraud campaign is also highlighted on that page.

CONCLUSION

In the midst of a relentless global pandemic, the American people are counting on law enforcement to safeguard the public and ensure that our States, cities, and communities are protected from individuals and organizations intent on exploiting the pandemic through fraud. This is why HSI launched Operation Stolen Promise, and why the men and women of HSI have worked day in and day out to identify, disrupt, and dismantle these schemes rapidly and effectively utilizing the unique and extensive tools at HSI's disposal.

HSI's work through Operation Stolen Promise has yielded tremendous statistical results in just a matter of months. These actions have kept unlawful pharmaceuticals, testing kits, and medical supplies out of the hands of American consumers; have prevented Americans from being victimized by financial scams; and have helped secure the integrity of the U.S. financial and trade systems. Despite being faced with an unprecedented global health crisis, HSI personnel throughout the country and around the world have remained dedicated to carrying out this important mission. HSI is proud of its role in responding to COVID-19 fraud and on the impact Operation Stolen Promise has made on the lives of the American public, which the men and women of HSI have sworn to protect and serve.

Thank you again for the opportunity to submit this testimony for the record.

QUESTIONS SUBMITTED FOR THE RECORD TO STEVE FRANCIS

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

CONNECTION TO FOREIGN GOVERNMENTS

Question. COVID-19 has given foreign governments the opportunity to engage in financial fraud schemes or other illicit criminal activity against the United States. For example, Federal law enforcement agencies have told us that the People's Republic of China is targeting research organizations working on COVID-19 vaccines.

During your agency's investigative efforts to stop illicit criminal activity associated with the virus, has HSI found any connection to foreign governments? If so, which ones? And, what kinds of illicit activity are these foreign actors engaged in?

Answer. To date, U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI) is not aware of any instances of a foreign government having direct involvement in an illicit coronavirus disease 2019 (COVID-19) scheme or activity against the United States.

CYBERSECURITY PARTNERS

Question. Is HSI working with its cybersecurity partners to alert the health-care, pharmaceutical, and research sectors of the threat of foreign interference? If so, please elaborate on these efforts.

Answer. ICE HSI Cyber Crimes Center (C3) has not received information related to the threat of foreign interference that could be used to alert the health-care, pharmaceutical, or research sectors. However, C3 is aware of other partners working on this issue; specifically CISA, as referenced on their website at <https://us-cert.cisa.gov/ncas/current-activity/2020/07/16/malicious-activity-targeting-covid-19-research-vaccine-development>. In the event that C3 receives information related to the threat of foreign interference that could be used to alert the health-care,

pharmaceutical, or research sectors in the future, it will alert the appropriate stakeholders.

C3 works closely with public and private cybersecurity partners as well as other domestic and international law enforcement agencies to prevent transnational criminal networks and malicious actors from exploiting the COVID-19 pandemic for illicit financial gains and other criminal activity. Additionally, ICE HSI is collaborating with the Internet Corporation for Assigned Names and Numbers and U.S. based domain registrars to identify, disrupt, and investigate malicious registration of domain names related to COVID-19, also known as Domain Name System fraud and abuse.

As of August 2020, ICE HSI referred over 11,000 COVID-19 suspected fraudulent domains for appropriate disruption action, including:

- Websites that were identified by ICE HSI as phishing websites impersonating legitimate businesses selling COVID-19 supplies and charitable organizations conducting COVID-19 fundraising. These websites were suspected of being set up to steal a victim's personally identifiable information.
- Websites that posed as COVID-19 informational websites but were identified by ICE HSI as being set up for the purpose of executing malware.
- Websites that were identified by ICE HSI as being set up for the purpose of selling COVID-19-related supplies (*i.e.*, personal protective equipment (PPE), hand sanitizers, disinfectant wipes, etc.) but never sent said products to the customer.

The ICE HSI-led Intellectual Property Rights Coordination Center (IPRC) takes an active role in protecting the U.S. health-care, pharmaceutical, and research sectors through consistent communication and information exchange with public and private-sector partners. The IPRC maintains relationships with pharmaceutical and medical supply companies such as Pfizer, Merck, Johnson & Johnson, and 3M. An open dialog is maintained to allow for the flow of information between government and partners to aid in identification of trends regarding counterfeit pharmaceuticals and PPE.

The IPRC has a strong working relationship with the U.S. Customs and Border Protection (CBP) National Targeting Center (NTC). The IPRC staff investigators at the NTC to assist in the exchange of information, which improves targeting by CBP analysts and results in the identification and seizure of counterfeit and illicit medicine and medical equipment.

The IPRC has 25 partner agencies to include the Food and Drug Administration (FDA) and Environmental Protection Agency (EPA). These relationships have been an integral part of responding to COVID-19-related fraud. Specifically, the EPA has taken the lead in the identification of unauthorized testing kits and in the identification of unauthorized pesticides used in virus shut-out lanyards/cards.

ICE HSI is proud of its current connections within the pharmaceutical and medical device community and views its continued outreach efforts as an integral part of the work done at the IPRC. Staff participate in presentations and discussions with private-sector associations to provide education and make new connections with companies that have a vested interest in combatting, or may be susceptible to, fraud. ICE HSI intends to continue to develop, engage, and leverage its important connections within the pharmaceutical and medical device communities.

CORPORATE PARTNERSHIPS

Question. What is the current status of this partnership? And, how is HSI communicating with these companies to facilitate the exchange of intelligence? Do you anticipate expanding this partnership to include additional companies? If not, why not?

Answer. The ICE HSI-led IPRC takes an active role in protecting the U.S. medical supply chain through consistent communication and information exchange with public and private-sector partners. The IPRC maintains relationships with pharmaceutical and medical supply companies such as Pfizer, Merck, Johnson & Johnson, and 3M. An open dialog is maintained to allow for the flow of information between government and partners to aid in identification of trends regarding counterfeit pharmaceuticals and personal protective equipment. The IPRC also has a strong working relationship with the CBP NTC. The IPRC maintains staffing of investigators at the NTC to assist in the exchange of information, which improves targeting

by CBP analysts and results in the identification and seizure of counterfeit and illicit medicine and medical equipment.

A robust outreach effort is an integral part of the work done at the IPRC and HSI intends to continue to develop, engage, and leverage its important connections within the pharmaceutical and medical device communities. IPRC staff participate in presentations and discussions with private sector associations to provide education and make new connections with companies that have a vested interest in combating fraud.

The ICE HSI C3 works closely with public and private cybersecurity partners, as well as other law enforcement agencies, to prevent transnational criminal networks and malicious actors from exploiting the COVID-19 pandemic for illicit financial gains and other criminal activity. To date, ICE HSI C3 has not received information from cybersecurity partners related to threats of foreign interference. ICE HSI C3 is collaborating with the Internet Corporation for Assigned Names and Numbers and U.S. based domain registrars to identify, disrupt, and investigate malicious registration of domain names related to COVID-19, also known as Domain Name System fraud and abuse.

COUNTERFEIT ORIGINATION

Question. Before the COVID-19 pandemic, over 60 percent of counterfeit goods originated in China or Hong Kong.

How has this changed during the COVID-19 pandemic? Where are COVID-19 infringing products originating from now?

Answer. Based on the seizures made in conjunction with ICE HSI partners at CBP, approximately 52 percent of items seized entering the United States that are determined to be prohibited COVID-19 products have originated in China or Hong Kong. To date, there have been a total of 49 countries of origin for such items, with these nations being the top 5: China/Hong Kong—52 percent; United Kingdom—7 percent; Nigeria—5 percent; Mexico—4 percent; and Thailand—3 percent.

In early April 2020, ICE HSI launched Operation Stolen Promise to disrupt individuals or organizations who attempt to exploit and profit from the COVID-19 pandemic. Utilizing ICE HSI's expertise within global trade investigations, financial fraud schemes, cyber-enabled crimes, and our international footprint, ICE HSI has accomplished the following (as of August 2020):

- Made over 1,000 seizures;
- Analyzed over 58,000 COVID-19-related domains/websites;
- Referred nearly 1,300 leads to domestic/international ICE HSI offices;
- Initiated over 600 criminal investigations;
- Executed 85 search warrants;
- Conducted 64 arrests;
- Secured 27 indictments;
- Seized over \$7.9 million in illicit proceeds;
- Seized over \$2.4 million relating to the Coronavirus Aid, Relief, and Economic Security (CARES) Act fraud; and
- Disrupted and/or recovered over \$17.9 million in fraudulent transactions related to illicit fraud schemes.

ORGANIZED CRIME

Question. Have you found any connections to organized crime such as MS-13 or other terrorist organizations?

Answer. ICE HSI is aware of cases involving COVID-19-related criminal activity that have been tied to organized crime groups and terrorist organizations.

HSI has seen organized crime groups attempt to capitalize on the pandemic through the sale of counterfeit/fraudulent medical items, such as test kits and PPE. HSI has not found any connection between MS-13 and COVID-19-related crime.

HSI has seen international terrorist organizations attempt to finance their activities through COVID-19 fraud scams perpetrated online. Additionally, HSI is aware of an investigation into a subject tied to domestic terrorism who was involved in CARES Act Fraud.

Due to the ongoing nature of these investigations and the fact that many of them are worked in conjunction with other agencies, HSI is unable to provide any additional details pertaining to these cases.

QUESTION SUBMITTED BY HON. RON WYDEN

COUNTERFEIT RESPIRATORS

Question. My State of Oregon relied on an emergency use authorization from the Food and Drug Administration to purchase respirators from China to protect medical personnel.

These respirators were supposed to meet the N95 standard for performance, but after they arrived in the U.S., they failed quality tests by the Federal agency that certifies safety equipment, the National Institute of Occupational Safety and Health, also known as NIOSH.

After failing the test, the FDA retracted its approval not just for the respirators Oregon bought, but for a significant number of other foreign manufacturers. NIOSH says that some of the Chinese manufacturers now claim the faulty respirators were counterfeit.

Either way, desperately needed imported equipment didn't meet the U.S. standards they were supposed to meet. Either way, the result is unacceptable.

Please explain what your agency is doing to track down how these substandard respirators got into the United States. To the extent possible, please clarify which respirators may have been counterfeit, which were simply not up to U.S. standards when they were made and sold.

What actions are being taken against the suppliers that provided that equipment?

Answer. ICE HSI launched Operation Stolen Promise to combat COVID-19-related fraud and other criminal activity. Operation Stolen Promise leverages and concentrates existing collaborative efforts among multiple Federal departments and agencies, along with business and industry representatives. Surging criminal activity surrounding the COVID-19 pandemic requires an equally robust investigative response to protect the American public.

Regarding respirators, ICE HSI works closely with its partners at the U.S. Food and Drug Administration (FDA), the National Institute for Occupational Safety and Health, and CBP to prevent violative medical devices and personal protective equipment from entering into U.S. commerce. If ICE HSI receives information that a supplier has imported or introduced a product into U.S. commerce that is counterfeit or otherwise violates U.S. laws or regulations, it may initiate an investigation. Investigations that conclude a supplier or product is in violation of U.S. laws or regulations may result in criminal or administrative charges, and/or the seizure of the violative product.

QUESTION SUBMITTED BY HON. BENJAMIN L. CARDIN

COUNTERFEIT PPE

Question. Maryland health providers have been fortunate to not have received exceptional amounts of counterfeit personal protective equipment like some other States. However, some of our long-term health facilities reported that they received an order of 6,000 medical gowns that were counterfeit. This senior care provider association returned the counterfeit gowns to the vendor and refused delivery of a subsequent order.

This same senior care provider association also reported that many Maryland long-term care facilities received gowns from FEMA that were not usable as effective personal protective equipment as they were actual bags with holes cut out for a head.

When a health provider receives a shipment of counterfeit PPE from a vendor, who should they report the issue to?

What steps have you taken to address counterfeit PPE and make the purchaser whole?

Answer. ICE HSI launched Operation Stolen Promise to combat COVID-19-related fraud and other criminal activity. Operation Stolen Promise intensifies collaboration with multiple Federal departments and agencies, along with business and industry representatives. Surging criminal activity surrounding the COVID-19 pandemic requires an equally robust investigative response to protect the American public.

ICE HSI works closely with its partners at the FDA and CBP to prevent the importation of substandard medical devices and PPE from entering United States commerce.

Anyone, including health-care providers, who suspects that they may have received a shipment of counterfeit PPE can provide information to ICE HSI at COVID19FRAUD@DHS.gov. When ICE HSI receives information alleging that a supplier has sold a product that is counterfeit, substandard, or otherwise violates United States laws, it initiates an investigation. Depending on the circumstances, an investigation may result in criminal charges, administrative charges, and/or simply the seizure of the violative product in order to prevent it reaching the public.

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

Good morning. I'd like to welcome everyone to the Finance Committee's hearing on "Protecting the Reliability of the U.S. Medical Supply Chain During the COVID-19 Pandemic." This is the first hearing of a series of hearings to discuss the integrity of our Nation's medical supply chain.

Today, we will hear from the Department of Homeland Security (DHS), and in a few days we will hear from private-sector stakeholders. This is an extremely important topic to discuss and one that impacts the safety of all Americans. It's Congress's responsibility to ensure that DHS upholds its responsibility to protect the public health by properly ensuring that Americans on the front line get safe and effective medical supplies.

I think we can all agree: the COVID-19 pandemic has exposed several vulnerabilities in our Nation's medical supply chain. Some of these vulnerabilities are new, while others have been around long before the pandemic and have been further exacerbated by this crisis. Indeed, I've been asking questions long before the pandemic brought these issues to the forefront of national debate. In November of last year, I finalized my oversight activities on the proliferation of counterfeit and other illicit goods sold on e-commerce platforms.

The ranking member and I issued a report on our findings and highlighted the threat counterfeits pose to our Nation's economic security, and the health and safety of Americans. We also highlighted that many counterfeits originate in China and Hong Kong. At this point, I think it's fair to say that China has serious quality control problems. It was evident then, and even more so now.

Before the coronavirus pandemic, hospitals and health-care workers could avoid purchasing counterfeits by tapping into tried-and-true supply chains. However, as the demand for PPE skyrocketed, some of these providers have had to go outside their normal supply chains to source supplies, and in some cases have inadvertently purchased fake, faulty, and even illicit medical supplies. The problem of counterfeit and faulty products is something that I've looked into for a very long time, dating back to when I was chairman of the Judiciary Committee.

As the virus began its foothold in the United States, I also sent a letter to Vice President Mike Pence and several other agency heads to express my concern that PPE shortages were allowing bad actors to take advantage of hospitals and health-care workers desperate for supplies. I've talked to hospitals all over the country and have heard stories of price gouging, shady middlemen, and PPE that was ordered and then never arrived, or was unusable. In my letter, I asked the administration to take this issue seriously and to prosecute bad actors to the fullest extent of the law.

Today, we'll hear from a representative from U.S. Immigration and Customs Enforcement's Homeland Security Investigations on their efforts to do just that. Before we hear from today's witnesses, I want to discuss the substance of today's hearing. We will discuss several issues confronting our Nation's supply chain as our country continues to battle the coronavirus pandemic. First, I want to go back to the beginning and expose the root cause of why the United States—and frankly, the world—is experiencing a breakdown of their supply chains.

China is the largest manufacturer of PPE in the world, with more than 40 percent of PPE manufactured there. In the beginning of the pandemic, China did the unthinkable. They turned off the taps of PPE manufacturing and heavily restricted their exports of PPE. The Chinese Government also directed its local and state governments to source more supplies from the international market. As global demand

soon spiked and China restricted exports, distributors and suppliers were unable to fulfill orders. As a result, some hospitals report estimated delays of 3 to 6 months for supplies.

Some pundits say China did what it did to address a domestic health crisis. However, it's important to remember that, in the beginning, China downplayed the seriousness of the coronavirus threat to the world while it redirected vast quantities of PPE towards its domestic needs. In the United States, China's decision to redirect medical supplies occurred when States, territories, localities, and tribes began to desperately need these critical supplies.

While China has since reversed course and allowed PPE to leave the country, the United States has continued to struggle to meet demand, with most of our supply chains heavily dependent on China or Mexico. We cannot allow our supply chains to rely so heavily on China, and I look forward to working with my colleagues on both sides of the aisle to discuss how we can diversify our supply chains and increase our domestic manufacturing capacity. I want to turn now to how shortages have affected hospitals and health-care workers.

Before the coronavirus pandemic, hospitals and health-care providers employed a "just-in-time" approach to sourcing supplies from trusted distributors. However, as the virus gained a foothold in the United States, everyone rushed to compete for supplies, further exacerbating the shortages. As a result, some health-care providers resorted to purchasing PPE from unverified suppliers, and some even turned to the Internet to source supplies. By doing so, these providers sometimes received fake, fraudulent, and even illicit goods not safe for use in treating patients with the coronavirus. In other cases, providers faced price gouging or hoarding. Fake N95 masks have become so prolific that 3M recently filed suit against several purported PPE sellers profiting from COVID-19 at the expense of the sick and vulnerable.

Large health-care systems have told me that the supply chain is doing better now, with more PPE coming in daily, which gives them the ability to avoid unverified suppliers altogether. However, smaller providers continue to face horrific shortages which may cause them to continue to turn to unverified suppliers, or even the Internet, to source supplies. Even more concerning is that smaller providers, like safety-net clinics and rural hospitals, tend to treat low-income families, a majority of which are African Americans and Latinos.

This population has been hit the hardest by the pandemic, and is four to five times more likely to be hospitalized for contracting the coronavirus. This is an issue that cannot be sugarcoated or spun for some political purpose. It's a fact. The black and brown community is suffering.

As members of Congress and stewards of the public trust, we must do everything in our power to protect this vulnerable population. This committee is considering several proposals to do just that. And one way we can help this vulnerable population is to do everything in our power to shore up the integrity of our Nation's supply chain and make sure that all hospitals and health-care providers get the quality supplies they need to treat COVID-19 patients.

With that said, I want to now turn to the Department of Homeland Security's efforts to protect the integrity of our Nation's supply chain, as we have witnesses before us today who can speak to this very issue. DHS and its components are engaged in an unprecedented, whole-of-government response to combat the coronavirus pandemic. Our Nation has not faced a pandemic like the coronavirus in more than 100 years.

Even so, we can't deny that the Federal Government's approach to emergency preparedness has always been fraught with problems, going back to President Obama's administration and beyond. This is not some partisan point. It's a fact. It also shows that no matter which party is in the White House, we can always do more to prepare.

Today, we will hear from witnesses who represent DHS's Office of Procurement, U.S. Customs and Border Protection, and ICE's Homeland Security Investigations. Thank you for being here. I look forward to hearing from all of you.

In closing, I want to say two things. First, I want to thank the DHS officials who work tirelessly to ensure the integrity of our Nation's supply chain, and for their efforts to ensure that those in most need get critical, quality medical supplies. Your job is incredibly difficult right now, but it is also incredibly important.

Second, we must come together to address vulnerabilities in our Nation's supply chain. I hope today we can have a good-faith discussion so that we can better understand what we, as a Congress, need to do to protect America's front-line workers and prepare our country for future national health emergencies.

SUBMITTED BY HON. MAGGIE HASSAN,
A U.S. SENATOR FROM NEW HAMSHIRE

White House COVID-19 Supply Chain Task Force
RADM John P. Polowczyk

Introduction:

**PREDECISIONAL &
DELIBERATIVE**

The demand estimates are at the high end of expectations to ensure medical workers, first responders, etc. do not go without necessary PPE during a future pandemic or Natural disasters.

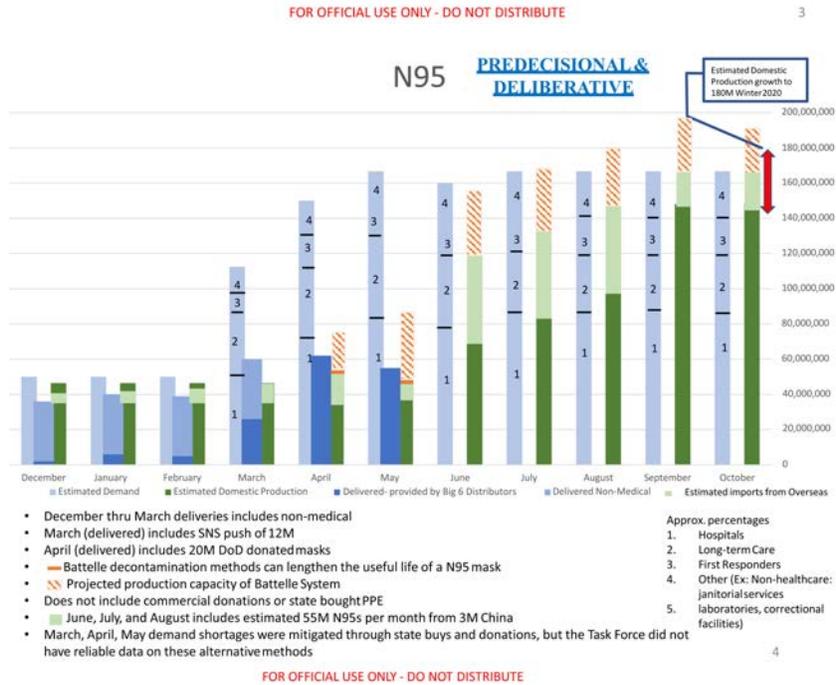
Included:

- "Our high end demand estimates" informed by:
 - Interagency analyses
 - Industry estimates
 - Historical demand data from industry and best available data from six major U.S. medical-surgical distributors
 - Historical manufacturing data
 - Exclusive of SNS needs
 - Steadily declining COVID hospitalization rates should reduce daily hospital PPE usage, but demand through summer may remain constant as hospitals and states replenish stockpiles, and to meet reopening requirements.
- "Estimated monthly production" informed by:
 - For N95 respirators: actual figures from 3M, Owens and Minor, Honeywell, Moldex, and Prestige Ameritech
 - For surgical masks, gloves, face shields, gowns: estimates calculated from the actuals and reported production percentages
 - Estimated overseas production are produced overseas and distributed domestically to satisfy requirements
 - Non- traditional suppliers estimated impact on production
 - Battelle decontamination methods can lengthen the useful life of a N95 mask
 - Historical manufacturing data
- "Delivered- provided by Big 6" informed by:
 - Best available distribution data of six major U.S. medical-surgical distributors
 - Big 6 Distributors makes up 90% of the U.S. medical-surgical distributors
 - Delivered – provided by Big 6" includes Air Bridge, other FEMA procurements, and the recent nursing home deliveries
 - Also accounted for in addition to deliveries:
 - Non- traditional suppliers for face shields
 - Boeing, Ford, Universities, etc.
 - Reusable gowns estimated shipments

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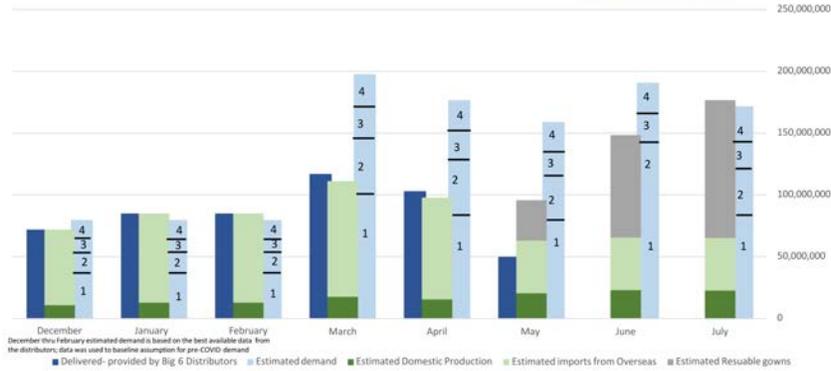
Not included in delivered data:

- Procurements by states
- Commercial donations
- Distribution data of other medical-surgical distributors
- Direct shipments from manufacturers



Gowns

PREDECISIONAL & DELIBERATIVE



- March (delivered) includes SNS push of 4.5M
- June: estimated demand subject to fluctuation
- The demand for gowns outpaces current US manufacturing capabilities.
- May, June and July may be reduced as reusable gowns enter and are accepted by medical community

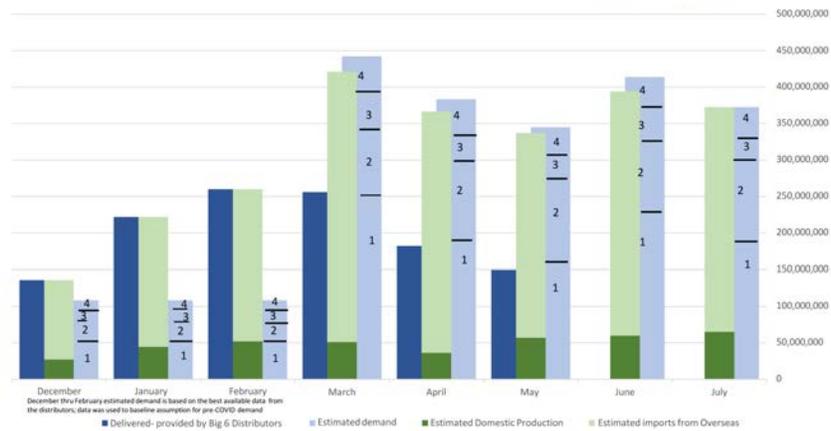
- Approx. percentages
1. Hospitals
 2. Long-term Care
 3. First Responders
 4. Other (Ex: Non-healthcare: janitorial services, laboratories, correctional facilities)

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5

Surgical Masks

PREDECISIONAL & DELIBERATIVE



- March (delivered) includes SNS push of 27M
- June: estimated demand subject to fluctuation
- The demand for surgical masks outpaces current US manufacturing capabilities pre-COVID.
- Month-over-month changes in demand can be attributed to the use of other face coverings

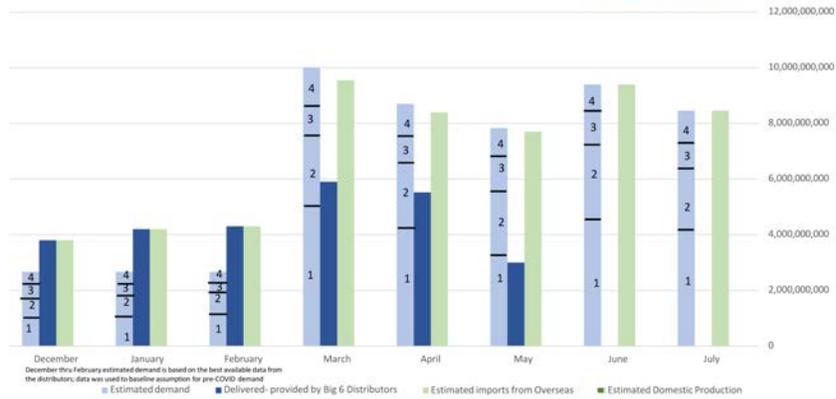
- Approx. percentages
1. Hospitals
 2. Long-term Care
 3. First Responders
 4. Other (Ex: Non-healthcare: janitorial services, laboratories, correctional facilities)

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Nitrile Gloves

PREDECISIONAL & DELIBERATIVE



- March (delivered) includes SNS push of 23M
- April (delivered) slightly lower due to challenges in overseas manufacturing
- June: estimated demand subject to fluctuation
- There is no U.S. based manufacturing for Nitrile Gloves.

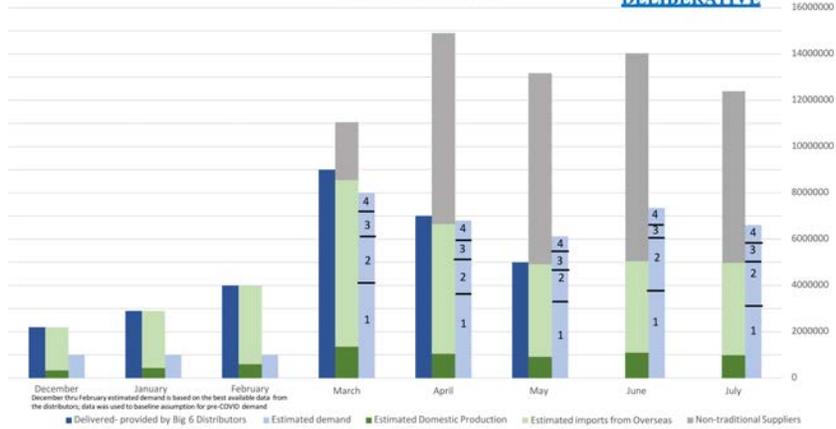
- Approx. percentages
1. Hospitals
 2. Long-term Care
 3. First Responders
 4. Other (Ex: Non-healthcare: janitorial services, laboratories, correctional facilities)

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Face Shields

PREDECISIONAL & DELIBERATIVE



- December thru February actual deliveries, March (delivered) includes SNS push of 5.4M
- June: estimated demand subject to fluctuation
- Non-traditional suppliers like Ford, Boeing, Universities etc.
- Month-over month changes in demand can be attributed to the use of other face coverings
- Ease of manufacturing from non-traditional suppliers expected to increase supply inside the United States

- Approx. percentages
1. Hospitals
 2. Long-term Care
 3. First Responders
 4. Other (Ex: Non-healthcare: janitorial services, laboratories, correctional facilities)

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PREPARED STATEMENT OF THOMAS F. OVERACKER, EXECUTIVE DIRECTOR, CARGO AND CONVEYANCE SECURITY, CUSTOMS AND BORDER PROTECTION, DEPARTMENT OF HOMELAND SECURITY

Chairman Grassley, Ranking Member Wyden, and members of the committee, it is my honor to appear before you today to discuss what U.S. Customs and Border Protection (CBP) is doing to ensure the integrity of medical supply chains and to facilitate the importation of vital medical supplies to support the fight against the COVID-19 pandemic in the United States.

The global scale of this pandemic has required a comprehensive response. CBP serves steadfastly on the frontlines, implementing and supporting the U.S. response, effectively managing travel and trade, and mitigating risk. Our efforts to expedite the import of legitimate cargo like medical supplies and protective equipment while also preventing the unlawful import of counterfeit, mislabeled, or unsafe products have become increasingly important during this pandemic. Expediting legitimate trade while protecting Americans from dangerous products are parallel and crucial efforts, and CBP has stepped up to the challenge of balancing them in order to protect American health and safety.

CBP acknowledges that a successful U.S. response demands strong partnerships with other government agencies, private-sector stakeholders, medical organizations, and our international counterparts. CBP has prioritized communication with all parties involved in the global medical supply chain. We are working with agencies like the Food and Drug Administration (FDA) and the Federal Emergency Management Agency (FEMA); importers, brokers, and carriers; State and local health agencies; medical organizations; and other stakeholders to ensure critical medical supplies and personal protective equipment (PPE) reach their intended destinations for the battle against COVID-19 here in the United States.

During fiscal year (FY) 2019, CBP processed 35.5 million entries valued at over \$2.7 trillion and more than 28.7 million imported cargo containers at U.S. ports of entry (POEs). Over the last 6 months and as a direct result of the global pandemic, CBP has seen a 12-percent decline in overall volume and a 13-percent decline in the value of imports when compared to the same period for 2019. These declines reached their peak in May when the volume and value of imports were 26-percent and 27-percent lower, respectively, than in May of last year.

While the U.S. is working with Canada, Mexico, and other international partners to implement certain border restrictions for non-essential travel, U.S. borders remain open for commerce, and CBP continues to facilitate legitimate commercial trade at POEs nationwide.

FACILITATING CRITICAL MEDICAL SUPPLIES

As the pandemic has evolved within the United States, demand for PPE, COVID-19 test kits, ventilators, and other medical supplies has increased. CBP has witnessed an unprecedented surge in imports of these medical products, in particular masks and gloves. In April alone, import quantities of medical commodities increased by 227 percent. The number of new actors in the supply chain has also dramatically increased. For example, while Malaysia remains the largest source country for surgical and medical gloves, the number of sellers of these products has increased by 128 percent. Similarly, while China remains the largest source country for masks, including N95 respirators, the number of consignees acquiring masks has increased by 160 percent.

The clearance process for medical products is complex; most medical devices and PPE are regulated commodities, and therefore must meet FDA or Environmental Protection Agency (EPA) standards for safety and efficacy. CBP regularly receives guidance from and shares data with other Federal agencies, including FDA and EPA, to ensure imported products meet these stringent requirements. CBP's existing partnerships with these Federal agencies became even more critical as the number of imports grew in response to COVID-19, and particularly as new suppliers and buyers began importing these products into the United States.

COVID-19 Cargo Resolution Team

With the significant growth in medical supply and PPE import volume, CBP leadership recognized the need for a centralized response team that could leverage the agency's expertise to respond to requests in real time. At the end of March, CBP created the COVID-19 Cargo Resolution Team (CCRT), composed of a network of subject matter experts from across the agency. The CCRT is managed by CBP's Pharmaceuticals, Health, and Chemicals Center of Excellence and Expertise, one of

10 industry-aligned centers designed to focus CBP's trade expertise and develop relationships with agencies, importers, and other stakeholders in specific industries. The Pharmaceuticals Center, with its longstanding expertise in the medical and health products industry, was well-positioned to manage the CBP response to this unprecedented strain on the global medical supply chain.

The CCRT has fulfilled a range of mission needs: triaging incoming requests from importers and customers; coordinating with Federal, State, and local government agencies; facilitating inbound shipments through POEs; and responding directly to inquiries about the import of PPE, COVID-19 test kits, ventilators, and other medical supplies. The CCRT coordinates with affected POEs and government agencies to ensure that legitimate shipments are not unnecessarily delayed. CBP also created an online portal to triage inquiries and provide up-to-date guidance from CBP and links to guidance from other government agencies. To date, the knowledge base has received more than 21,000 views.

One of the CCRT's most important partners is the FDA, which has regulatory authority over and expertise in many medical and PPE products. The CCRT interacts daily with FDA leadership and staff, sharing data needed to clear inbound shipments, identifying proper product labels and classification, and ensuring that imported supplies meet U.S. safety standards. The CCRT is also able to direct certain inquiries about FDA regulations to FDA's own response team, which ensures that importers meet key data requirements and reduces potential shipment delays.

The CCRT is also working with the U.S. Department of Health and Human Services (HHS) to facilitate importations of equipment and materials in support of Operation Warp Speed, which aims to deliver 300 million doses of a safe, effective vaccine for COVID-19 by January 2021 as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (collectively known as countermeasures).¹

To date, the CCRT has fielded approximately 2,500 incoming inquiries, which range from providing guidance on importing PPE, resolving holds, or expediting import release of medical supplies, to facilitating donations of PPE to U.S. recipients. The efforts of the CCRT, working with our interagency and private sector partners, have helped secure the importation of approximately \$1.2 billion in medical supplies for the COVID-19 response.

The Supply Chain Task Force/Project Air Bridge

CBP also worked with FEMA's Supply Chain Stabilization Task Force on Project Air Bridge, which significantly sped up the delivery of high-demand medical and PPE supplies from overseas manufacturers. Project Air Bridge cut the amount of time it took for American cities to receive supplies from manufacturers abroad from months to days. CBP worked closely with FEMA to identify the flights, screen the importers and shipments, alert the relevant arrival airports, and ensure the cargo was cleared and released as quickly as possible upon arrival into the United States. The program concluded on July 1, but retains the ability to be reactivated in accordance with shifting conditions. During the time it operated, CBP successfully cleared 416 Project Air Bridge and other FEMA procurement flights from 14 countries at 17 different U.S. airports, and facilitated the delivery of 1.3 billion pieces of PPE.

Customs Trade Partnership Against Terrorism

CBP is also leveraging existing partnerships with industry to facilitate the import of legitimate medical supplies. The Customs-Trade Partnership Against Terrorism (CTPAT) is a voluntary public-private sector partnership program that was established in 2001. This program allows member companies to meet rigorous security criteria and vetting standards in return for enhanced facilitation, including expedited CBP processing.

Today, there are more than 11,600 certified partners who have agreed to work with CBP to protect the supply chain, identify security gaps, and implement specific security measures and best practices. CTPAT members account for approximately 54.3 percent (by value) of all U.S. imports, and the compliance rate of CTPAT members with the program's overall requirements, including having to successfully pass a CTPAT validation, is 97.5 percent. Of the members, more than 3,900 are U.S. importers—that is more than 34 percent of the total membership. Forty-one of these importers are part of the medical supply chain.

¹U.S. Department of Health and Human Services, "Fact Sheet: Explaining Operation Warp Speed," June 16, 2020, <https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html> (July 17, 2020).

In response to the COVID-19 pandemic, CBP's CTPAT team worked closely with CTPAT members from the medical manufacturing and supply industry, ensuring that some of the largest importers of PPE and medical equipment in the United States were able to expedite clearance of these critical goods when needed most. This trusted trade partnership is critical to mitigating supply chain risks, and ensuring that safe, legitimate supplies move quickly into U.S. markets.

PROTECTING U.S. MEDICAL SUPPLIES

CBP also is supporting FEMA by identifying outbound shipments subject to relevant executive orders regarding the Defense Production Act, working with the relevant exporters and CBP personnel on the ground to identify and examine the shipments, and providing relevant information to FEMA for review and adjudication.

Timely reviews have been a priority in this process. CBP is expediting data sharing, review, and cargo examination as much as possible to ensure FEMA can make decisions quickly. As of July 22nd, CBP had identified and referred 159 export supply shipments to FEMA. Of those, 142 were subsequently cleared for export and 16 were canceled and returned to the U.S. supply chain. Under this authority, FEMA and CBP have returned 3.6 million protective masks and nearly 150,000 sets of gloves to U.S. markets.

SAFEGUARDING THE MEDICAL SUPPLY CHAIN

As a core component of CBP's mission, ensuring the safety and legitimacy of imported goods has become increasingly important in the context of the COVID-19 pandemic. With imports of medical supplies and PPE growing dramatically to meet the U.S. demand, so too did attempts to circumvent the Nation's trade and customs laws. CBP has seen an increasing number of potentially dangerous counterfeit or unauthorized COVID-related products. Since the pandemic began until the end of June, CBP has seized more than 120,000 unlawful COVID-19 test kits in 339 separate incidents. These items were either refused admission into the U.S. because they did not meet U.S. regulatory or legal requirements, or they were potentially unlicensed. As of June 30, we have also seized more than 10 million counterfeit face masks in 80 separate incidents; 3,000 EPA-prohibited anti-virus lanyards in 95 incidents; 24,000 FDA-prohibited chloroquine and hydrochloroquine tablets in 148 incidents; and 4,000 tablets of counterfeit or unsafe antibiotics, such as azithromycin, in 76 incidents.

CBP has also increased targeting for possible counterfeit or infringing merchandise in the international mail and express consignment cargo environments. We are leveraging the trade industry and other government agency partnerships to gather essential information that is being used to target and prevent illicit actors from attempting to circumvent import requirements or take advantage of the current COVID-19 pandemic.

Targeting High-Risk Shipments

CBP coordinates with U.S. industries, 49 agency partners, and foreign governments to detect anomalies, trends, and violations in the global supply chain, to target high-risk shipments, and to promote compliance. CBP's National Targeting Center (NTC) uses state-of-the-art technologies and highly skilled specialists to identify, target, and coordinate examination of high-risk shipments while permitting legitimate trade to flow unimpeded. The NTC leverages classified, law enforcement, commercial, and open-source data, as well as deep subject-matter expertise, to assess and segment risk at every stage in the supply chain. This enables NTC staff to identify high-risk shipments at the earliest possible point prior to arrival in the United States. The analysis and information coming out of the NTC not only helps stop potentially dangerous inbound shipments, but also provides critical information for longer-term investigations into bad actors behind those shipments.

To bolster its targeting mission, the NTC collaborates daily with critical partners, including U.S. Immigration and Customs Enforcement Homeland Security Investigations (ICE-HSI), the U.S. Drug Enforcement Administration, the Federal Bureau of Investigation, the U.S. Postal Inspection Service (USPIS), and members of the intelligence community. ICE-HSI and USPIS investigative case data are fused with CBP targeting information to bolster investigations targeting illicit narcotics smuggling and trafficking organizations. Moreover, the NTC works in close coordination with several pertinent task forces, including the Organized Crime Drug Enforcement Task Forces, the High Intensity Drug Trafficking Areas, the Joint Interagency Task Force-West, the DHS Joint Task Force-West, and DHS Joint Task Force Investigations. Effective targeting and interdiction prevents inadmissible

high-risk passengers, cargo, agriculture, and bioterrorism threats from reaching U.S. POEs. This extends our border security initiatives outward, making our borders not the first line of defense, but one of many.

The NTC has established the Integrated Trade Targeting Network (ITTN) as an integrated operational network among all of CBP's trade targeting assets to improve communications, coordinate actions, and standardize procedures for more effective trade targeting. In addition to the ITTN, the NTC also partners with ICE-HSI via the Tactical Trade Targeting Unit to utilize all available trade data for further research to bolster trade and target questionable operations related to fraud and trade-based money-laundering investigations.

As part of the ITTN, the Commercial Targeting and Analysis Center (CTAC), also led by CBP, is composed of multiple, co-located government agencies responsible for targeting and intercepting commercial shipments that pose a threat to the health and safety of Americans. Twelve Federal agencies—including the FDA, EPA, and our colleagues at ICE-HSI—share targeting information as part of CTAC, and to prevent, deter, interdict, and investigate violations of U.S. import and export laws.

Advance Data Collection

Key to these targeting efforts are the data CBP collects. An important element of CBP's layered security strategy is obtaining advance information to help identify shipments that pose a higher risk of containing contraband. Under section 343 of the Trade Act of 2002, as amended, and under the Security and Accountability for Every Port Act or SAFE Port Act of 2006, CBP has the legal authority to collect key cargo data elements provided by air, sea, and land commercial transport companies. This information is automatically fed into the Automated Targeting System, a secure intranet-based enforcement and decision-support system that compares cargo and conveyance information against intelligence and other enforcement data.

Safeguarding the E-Commerce Supply Chain

Over the past 5 years, e-commerce has grown exponentially as consumers make more direct purchases online. These purchases are typically shipped directly to consumers and cross our borders through multiple modes of transportation. While international mail volumes peaked in 2017, mail still accounts for over 80 percent of these shipments. Over the last 5 years, air, truck, and express consignment shipments have increase by 79 percent. Pre-COVID, CBP processed approximately 1.9 million shipments per day across all modes, with 91 percent of those valued at \$800 or less. Criminals are attempting to exploit this volume, presenting the United States with economic risks in the form of intellectual property rights (IPR) infringement, as well as safety risks from poor quality and untested consumer products, such as fraudulent or prohibited COVID-19 products and PPE.

CBP has taken an active approach to addressing these trends. For example, late last year, CBP initiated an e-commerce data pilot pertaining to low-value, de minimis shipments of \$800 or less. Under this pilot, CBP is receiving certain advance data from e-commerce supply chain partners, including online marketplaces, to help identify the entity causing the shipment to move, the final recipient, and the contents of the package. The pilot's participants represent a wide range of e-commerce supply-chain companies including eBay, FedEx, DHL, and UPS, with others set to begin sharing data in the near future. Partnerships with e-commerce leaders are critical for identifying counterfeit and unsafe medical supplies and PPE shipments before they reach U.S. consumers, as well as stopping those responsible for attempting to circumvent U.S. safety standards.

Interagency Enforcement Efforts

CBP works extensively with other U.S. Federal and foreign government agencies to address transnational threats at POEs, international mail facilities, and express consignment facilities. Joint operations and task forces conducted under the auspices of multi-agency enforcement teams enhance targeting, detection, and interdiction capabilities. CBP works closely with ICE-HSI to conduct Operation Stolen Promise (OSP), targeting the evolving threat posed by COVID-19-related fraud and criminal activity. OSP has resulted in an array of investigations, seizures of illicit products and proceeds, arrests of criminals engaged in fraud, and a number of website domain seizures.

CBP is also a member of the Department of Justice's (DOJ) Consumer Fraud Coordination Workgroup. This workgroup is investigating COVID-related fraud schemes, many of which involve the fraudulent import or sale of medical products or PPE. CBP's data and information sharing assists DOJ efforts to pursue and shut down criminal actors and networks.

Forced Labor Enforcement

U.S. law prohibits the entry of goods produced in whole or in part with forced labor.² In September 2019, CBP issued a withhold release order (WRO) on a Malaysian manufacturer of rubber gloves, WRP Asia Pacific Berhad (BHD), based on reasonable suspicion that the gloves imported into the United States were produced with forced labor and in violation of U.S. law. Over the next 6 months, CBP worked with the manufacturer to successfully remediate the forced labor conditions. Based upon information demonstrating the manufacturer's successful efforts to remediate those conditions, CBP revoked the WRO on March 24th. CBP continues to examine the medical supply chain for forced labor. On July 15th, CBP issued a WRO on two more Malaysian rubber glove manufacturers, Top Glove BHD and TG Medical BHD, based on reasonable suspicion that their rubber gloves were being produced with forced labor. These enforcement efforts align with Congress's mandate that CBP takes action regardless of U.S. consumptive demand.

Additionally, Federal Acquisition Regulations prohibit Federal contractors from engaging in trafficking in persons, and include a prohibition on the use of forced labor. These regulations also prohibit Federal agencies from acquiring products made with forced or indentured child labor. These actions send a clear and direct message to the international trade community that the illicit, inhumane, and exploitative practice of forced labor will not be tolerated in U.S. supply chains.

CBP'S AGENCY-WIDE RESPONSE TO THE PANDEMIC

CBP continues to prioritize information sharing and communication with not only other government agencies, but industry as well. CBP has created a dedicated website³ and contact points for private industry and other government agencies to easily find answers on COVID-19 product admissibility and import guidance, cargo hold and facilitation, classification, and duties. This information enables new and existing importers to effectively and expediently navigate the import process during this unprecedented time. Meanwhile, we continue to look for other ways to assist private-sector stakeholders.

In an executive order signed on April 18th, the President provided the Secretary of the Department of the Treasury authority to extend temporarily deadlines on certain payments of duties and taxes for importers suffering significant financial hardship due to the pandemic.⁴ This important step provided American companies with financial flexibility while ensuring that revenue owed to the U.S. government will still be paid.

CONCLUSION

CBP continues to carry out its mission of facilitating and safeguarding the global supply chain, and has increased its focus on the critical medical supply chain and products needed for the Nation's response. The agency's targeting, data-collection, interagency partnerships, and collaboration with trade stakeholders bolster the efforts of the men and women on the front lines of CBP's trade mission. CBP's dedicated front-line personnel are vigilantly on the lookout for counterfeit, substandard, and unapproved COVID-19 products like PPE, pharmaceuticals, and test kits. CBP's agents, officers, and specialists remain committed to safeguarding our border and facilitating the flow of legitimate trade. CBP continues to stand guard at U.S. borders to ensure the safety and health of all Americans.

Thank you for the opportunity to testify today, and I look forward to your questions.

² 19 U.S.C. § 1307.

³ *Imports.cbp.gov*.

⁴ White House, "Executive Order on National Emergency Authority to Temporarily Extend Deadlines for Certain Estimated Payments," April 19, 2020, <https://www.whitehouse.gov/presidential-actions/executive-order-national-emergency-authority-temporarily-extend-deadlines-certain-estimated-payments/> (July 15, 2020).

QUESTIONS SUBMITTED FOR THE RECORD TO THOMAS F. OVERACKER

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

EDUCATING PORT PERSONNEL

Question. In your testimony, you indicated that bad actors are trying to profit from the coronavirus pandemic by introducing unauthorized, unproven, and potentially unsafe goods into the United States' supply chain. It appears that they are targeting us when we are at our greatest need.

Can you please describe how CBP is educating port personnel on COVID-19 illicit or infringing products?

Answer. U.S. Customs and Border Protection (CBP) provided information to port and Center of Excellence and Expertise personnel regarding trends and intelligence about illicit or infringing products through memoranda and guidance documents. Additionally, webinars and virtual training sessions were conducted that provided information on COVID-19 illicit or infringing products to port personnel.

As part of its continuous efforts to educate port personnel on fraudulent imports, CBP has several programs including providing Intellectual Property Rights (IPR) specific training to port personnel as well as virtual webinars, which connect rights holders with the ports and Centers of Excellence directly.

Question. How many of these seizures occur in the international mail and express shipment environment?

Answer. Please see table below for the data from January 1, 2020 to July 31, 2020 on COVID-19-related seizures in the international mail and express shipping environment. This data includes illicit goods of the following sorts: COVID-19 diagnostic test kits, antibody test kits, masks, chloroquine, hydroxychloroquine, azithromycin, respiratory equipment and ventilators, hand sanitizer, and virus shut-out lanyards.

International Mail	Seizures	Quantity	Express Shipments	Seizures	Quantity
COVID-19-related goods	192	23,901	COVID-19-related goods	481	595,123

ENGAGING WITH MANUFACTURERS

Question. How is CBP engaging with intellectual property right holders, distributors, suppliers, common carriers, and other interested parties on COVID-19 infringing products?

Answer. In response to the COVID-19 pandemic, CBP's Pharmaceutical, Health, and Chemical Center of Excellence and Expertise (PHC Center) reached out to its industry partners and gathered information on legitimate U.S. Food and Drug Administration (FDA)-approved, -cleared, or -authorized COVID-19 test kits, treatments for COVID-19, and other related COVID-19 items. Eight industry partners provided information about their COVID-19-related items and shipping procedures, allowing the PHC Center to generate and share several informational reports within the CBP Office of Field Operations (OFO) and the CBP Office of Trade.

CBP has worked to develop and disseminate relevant guidance and educational materials for Federal employees, the trade community, and the U.S. public regarding COVID-19-related goods and to promote consumer awareness of safety standards and informed compliance by commercial entities contributing to emergency response. When the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health (NIOSH) becomes aware of counterfeit respirators or those misrepresenting NIOSH approval on the market, the masks are posted on the NIOSH website to alert users, purchasers, and manufacturers. The CBP Commercial Targeting and Analysis Center (CTAC) and the PHC Center have been ongoing sources of intelligence for NIOSH regarding bad actors and online vendors of counterfeit products, which can be found online: <https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html>.

Additionally, CBP launched a public-facing site for CBP COVID-19 updates and announcements: www.cbp.gov/newsroom/coronavirus. This website consolidates COVID-19-related information with an interface to trade facilitation and trade security, including updates to Federal agency guidance regarding importation of personal protective equipment (PPE) and medical supplies. It also provides consumer

awareness for COVID–19 safety: Consumer Awareness for COVID–19 Safety guidelines warning American consumers about online sellers of counterfeit or sub-standard sanitation products and safety equipment. CBP has also used social media platforms such as Twitter to keep the public up-to-date on information surrounding IPR health- and safety-related seizures as well as the harm that these IPR violative goods pose to the American public. This information can be also found on Twitter—@cbptradegov.

Question. Is CBP engaging with 3M, Honeywell, and other PPE manufacturers? If so, please provide us a list of manufacturers CBP has engaged with and give us an update on those engagements.

Answer. On March 24, 2020, the Industrial and Manufactured Materials Center of Excellence and Expertise (IMM Center) participated in a meeting with 3M’s Trademark Counsel and Trade Compliance personnel to gather intelligence from 3M to strategically develop targeting parameters and identify and mitigate cargo delays. Joining the IMM Center were colleagues from the Miami National Threat Analysis Center (NTAC). After further review, the IMM Center developed the information into an IPR enforcement alert distributed to various OFO and Office of Trade component offices.

The IMM Center and Miami NTAC have developed targeting parameters to identify counterfeit 3M N95 respirators. The IMM Center continues to work with 3M to mitigate delays or impacts with cargo entering the United States. To date, IMM Center partners have not experienced any delays or impacts with cargo entering the United States.

The IMM Center continues to reach out to partnership accounts to obtain advance information on the importation of COVID–19 response materials (*e.g.*, PPE, sanitary supplies) in an effort to facilitate the importation of legitimate goods from our trusted partners.

SECURING THE SUPPLY CHAIN

Question. What steps is your agency taking to secure the U.S. medical supply chain as we go into fall and beyond?

Answer. Through active participation in COVID–19-related task forces and working groups led by the U.S. Department of Justice, FDA, and U.S. Immigration and Customs Enforcement’s (ICE) Homeland Security Investigations (HSI), CBP obtains critical information that increases the effectiveness of efforts to target illicit COVID–19-related products and will continue to help to secure the U.S. medical supply chain moving forward.

FORCED LABOR PROGRAMS

Question. CBP has previously blocked Chinese imports that were a product of forced labor. To be specific, the People’s Republic of China has been placing Uighurs, a Muslim minority, in “reeducation” camps and utilizing their forced labor.

Generally, how do we ensure that Uighurs and other oppressed populations are not part of our medical supply chain?

Answer. DHS is committed to enforcing against the People’s Republic of China’s serious human rights abuses, including forced labor, against Uyghurs and other ethnic and religious minorities. Both CBP and ICE are receiving and reviewing information on forced labor in China. Information is widely available that detail the People’s Republic of China’s use of forced and prison labor in China. Tracing medical goods produced with forced labor in the People’s Republic of China to the United States is challenged by the limited transparency of supply chains, availability of information, and ability to verify reporting. CBP collaborates with other U.S. agencies to identify goods that might be produced with forced labor.

Any type of goods, including medical goods, produced with forced labor are prohibited from importation into the United States. Companies should understand the legal and compliance risks when sourcing from China. Importers have the duty to exercise reasonable care and due diligence to ensure that goods produced with forced labor do not enter their supply chains. Tracing medical goods produced with forced labor in the People’s Republic of China to the United States is challenging due to limitations regarding the transparency of supply chains, availability of information, and ability to verify reporting. Information is widely available that details the People’s Republic of China’s use of forced and prison labor in China. Companies should understand the legal and compliance risks when sourcing from China.

CBP is taking enforcement action to the extent possible. Charged with enforcing 19 U.S.C. § 1307, CBP has issued multiple withhold release orders (WROs) on goods produced by forced Uyghur labor. The most updated list of WROs can be found at the *CBP.gov* website. CBP will continue to issue WROs when information reasonably indicates that goods produced with forced labor are being, or are likely to be, imported into the United States.

Question. How can we ensure that the products we need most are not mass produced by those in Chinese reeducation facilities or other forced labor programs?

Answer. DHS is taking enforcement action or developing cases for enforcement action against forced labor connected to mass internment camps in China, given that this remains a serious trade and human rights issue. Importers must ensure their supply chains are free of forced labor; failing to do so may result in administrative, civil, and criminal consequences. Accurate, open-source reporting about labor conditions overseas and transparency of company supply chains can help importers identify and remediate forced labor found in supply chains. Importers should use available information to exercise reasonable care to ensure they do not import goods produced with forced labor, and they must factor forced labor into a company's risk assessments and corporate compliance program. CBP will continue to investigate and take enforcement action on any goods produced with forced labor.

RULEMAKING STATUS

Question. Last year, Ranking Member Wyden and I issued a bipartisan report on counterfeits sold on e-commerce platforms. We found that certain legal barriers prevent CBP from sharing packing information with anyone other than the importer on record. We also learned that this information could help identify high-volume sellers, who often flood the supply chain with fake or faulty products. I imagine these same types of sellers are now trying to profit off the coronavirus pandemic.

Earlier this year, CBP indicated its intent to create a procedure for the disclosure of information otherwise protected by the Trade Secrets Act which would address this very issue. Can you tell us the status of this rulemaking?

Answer. Consistent with the U.S. Department of Homeland Security (DHS) *Report on Combating Trafficking in Counterfeit and Pirated Goods*, CBP is working with its interagency partners to evaluate potential regulatory changes that would allow for the enhanced information sharing you refer to. CBP is assessing additional statutory authorities that may be required to share information with non-traditional actors, such as online platforms.

CBP is finalizing its responses to public comments on the *Proposed Rule on Enforcement of Copyrights and the Digital Millennium Copyright Act* (October 16, 2019; 84 FR 55251), which concerns advanced information-sharing with respect to the seizure of circumvention devices and other copyright-infringing goods. Six public comments were received and are in review. The comments will be addressed in a final rule, which will be developed during Fiscal Year 2021.

Question. And, are you working with stakeholders during this process?

Answer. CBP has been working with the trade community, including online marketplaces, to identify potential areas for improved information sharing. Notably, CBP recently convened a task force group of trade participants that, among other focus areas, will explore information-sharing opportunities within CBP's existing statutory and regulatory authorities. Moreover, the public has a two-month window to comment on the Proposed Rule on Enforcement of Copyrights and Digital Millennium Copyright Act.

LEGAL BARRIERS

Question. Are there any other legal barriers that are preventing you from sharing information with right holders on COVID-19 infringing products?

Answer. There are generally no legal barriers preventing the sharing of certain information with right holders on COVID-19 infringing products, assuming that the right holder has followed the correct procedures. Specifically, if the trademarks and copyrights that are suspected of being infringed are federally registered and have been recorded with CBP, 19 CFR part 133 provides for extensive information sharing with right holders. In the context of copyrights, in accordance with section 304 of the Trade Facilitation and Trade Enforcement Act of 2015, CBP permits unregistered copyrights to be recorded for a period of 6 months as long as the applicant

includes evidence that it has a pending application with the U.S. Copyright Office, with the option of an additional 6-month extension.

QUESTIONS SUBMITTED BY HON. RON WYDEN

PPE PROBLEMS

Question. Prior to the coronavirus pandemic, nearly 50 percent of face shields, protective garments, masks, gloves, and goggles were imported from China. The U.S. was even more dependent on China for some other types of personal protective equipment like face masks.

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

Answer. CBP has always placed emphasis on Priority Trade Issues (PTIs), which are high-risk areas that can cause significant revenue loss, harm the U.S. economy, and/or threaten the health and safety of the American people. IPR and Import Safety are both PTIs. Additionally, depending on the seizure trends that we observe from year to year, CBP re-focuses its efforts to adapt to the agile nature of counterfeits.

As a result, CBP consistently works to address health and safety threats that counterfeit goods pose to American consumers. Counterfeit goods, including fraudulent COVID-19-related PPE, can affect the health and safety of the public and, as such, are a focus in CBP's enforcement efforts.

Question. Or is the issue around counterfeit or fraudulent PPE entirely driven by the massive surge in demand for PPE and the administration's failure to properly stockpile equipment prior to the pandemic, and its ongoing failure to procure quality safety equipment as the pandemic continued?

Answer. As noted above, because IPR and Health and Safety are PTIs, CBP works to address health and safety threats that counterfeit goods pose to American consumers based on three areas of emphasis: (1) targeting, intercepting, and taking meaningful enforcement actions on imports of counterfeit and dangerous imports; (2) interagency facilitation and expedited clearance of large shipments of PPE from legitimate vendors and international donors; and (3) development and dissemination of guidance and educational materials for Federal employees, the trade community, and U.S. public. Depending on the seizure trends that we observe from year to year, CBP re-focuses its efforts to adapt to the agile nature of counterfeits.

FORCED LABOR PROGRAMS

Question. Recent reporting has revealed that the United States buyers have received PPE made by Chinese companies who participate in a government-sponsored forced labor program. Federal law prohibits imports of products manufactured using forced labor and subjects such products to exclusion or seizure.

Why were PPE products manufactured using forced labor allowed to be imported into the United States in violation of Federal law?

Answer. Importing goods produced with forced labor is a violation of Federal law, and companies and individuals may face administrative, civil, and criminal consequences. If goods produced with forced labor were previously imported into the United States, there is still the possibility for administrative, civil, and criminal consequences for those who violated Federal law.

Both CBP and ICE are receiving and reviewing information on forced labor in China. CBP is aggressively pursuing allegations received with the many challenges and limited visibility that the Chinese supply chains bring. Of the thirteen WROs CBP issued this fiscal year, nine were issued to detain products from China. Eight were specific to the Xinjiang region. Additionally, CBP collected civil penalties on Chinese imports made with forced labor. This action is the first forced labor penalty that the agency has issued, and demonstrates another enforcement tool in CBP's ongoing effort to prevent goods made with forced labor from entering the United States.

Importers have the duty to exercise reasonable care and due diligence to ensure that goods produced with forced labor do not enter their supply chains. Tracing goods produced with forced labor in China to the United States is challenged by lim-

ited supply-chain transparency, availability of information, and accuracy of reporting.

CBP works collaboratively with the U.S. interagency, nongovernmental, and civil society organizations to identify goods of highest risk. CBP publicizes its strong interest in receiving allegations of goods produced with forced labor in U.S. supply chains.

Question. Why weren't such products blocked at the border and/or seized?

Answer. Unlike counterfeit goods and other violative merchandise, goods produced with forced labor generally cannot be identified by examination upon arrival at a U.S. port of entry. CBP must have reasonable suspicion that forced labor is used in the production or manufacture of U.S. imports before shipments can be detained. Reasonable suspicion is realized through research that results in a WRO. A Finding, which is a seizure order, requires a higher standard of evidence than a WRO.

Question. Is DHS and/or CBP investigating these apparently illegal imports?

Answer. Both CBP and ICE are receiving and reviewing information on forced labor in China. CBP and ICE are aware of allegations about PPE manufactured under forced labor conditions by Chinese companies. CBP will aggressively pursue enforcement action where evidence reasonably indicates that these goods from China are manufactured with forced labor and imported into the United States.

Question. Please explain what steps CBP is taking to ensure that PPE and other medical supplies procured in response to COVID-19 aren't produced with forced labor.

Answer. Under the Federal Acquisition Regulation, U.S. Government departments and agencies must conduct due diligence to eliminate the risks of forced labor in their procurement supply chains. CBP notifies departments or agencies when entities affected by a forced labor enforcement action is discovered in their procurement supply chain.

Question. What improvements could be made to ensure the U.S. does not facilitate forced labor?

Answer. Importers have the duty to exercise reasonable care and due diligence to ensure that goods produced with forced labor do not enter their supply chains. Increased supply chain transparency, through increased disclosure requirements, may improve the traceability of goods produced with forced labor and imported into the U.S.

To better understand complex supply chains and financial and political relationships of business entities operating in or connected to the Xinjiang Uygur Autonomous Region (XUAR) and China, a prioritized level of effort to develop intelligence and analyze information across the Intelligence Community and Federal interagency is needed.

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN

STOPPING COUNTERFEIT GOODS

Question. In the port of Baltimore and other mid-Atlantic ports, DHS Customs and Border Protection officials have continued to seize counterfeit and unapproved COVID-19 protective equipment and medications. Such seizures have included unapproved and counterfeit COVID-19 test kits, counterfeit N95 respirator masks, counterfeit ACCU-CHEK test strips, and unapproved and potentially counterfeit medicines, including Hydroxychloroquine Sulfate, Chloroquine, Azithromycin, Lianhua Qingwen and Liushen Jiaonang.

I have noticed that these products have come from all over the world, including China, South Korea, Turkey, Saudi Arabia, Nigeria, Senegal, Germany, and the United Kingdom, and these products were heading to numerous States in the mid-Atlantic region and throughout the United States.

What tactics or techniques have you found to be most effective in stopping the importation of these counterfeit goods?

Answer. CBP and interagency efforts to facilitate trade in critical medical and protective supplies as well as efforts to identify and intercept non-compliant, sub-

standard, unsafe, and/or counterfeit PPE and Medical Countermeasures (MCM) imports has proven effective.

CBP's information sharing and advance targeting nets efforts are the most meaningful enforcement action on imports of violative and potentially dangerous COVID-19-related materials such as fraudulent, illicit, or otherwise substandard test kits, ventilators, and disinfectants and pesticides (anti-viral and anti-bacterial). Since the outset of the COVID-19 pandemic response, CBP has leveraged real-time intelligence from partners serving with CBP's CTAC—most notably FDA, the U.S. Environmental Protection Agency, and ICE HSI—to identify areas of highest risk and to inform CBP National Targeting Center and PHC Center targeting on fraudulent and substandard COVID-19 PPE and medical supplies.

CBP is also an active contributor to the interagency COVID-19 consumer fraud working group led by the DOJ, whose work has led to several recent arrests for sales of illegal COVID-19 imports. For additional information, go to <https://www.justice.gov/usao-ndga/pr/georgia-resident-arrested-selling-illegal-products-claiming-protect-against-viruses> and <https://www.justice.gov/usao-cdca/pr/uk-national-charged-shipping-mislabeled-and-unapproved-treatments-patients-suffering>.

This interagency facilitation expedited clearance of large-scale shipments of critical medical supplies and PPE from legitimate vendors and international donors, through newly established structures like CBP's COVID-19 Coordinated Response Team and the State Department and FEMA-led International Resources Coordination Group (IRCG).

CBP efforts to streamline the entry of legitimate shipments result in the allocation of safe and plentiful PPE and MCM to health-care providers and other front-line users, and enable the U.S. Government to focus surveillance on bad actors and high-risk areas. This risk-calibrated approach was essential, and CBP plans to maintain this strategy, given the massive uptick in shipments of PPE this year.

Through its participation in the IRCG, CBP continues to facilitate the importation of donations of PPE from other foreign governments and hundreds of private-sector donors. CBP also engages the trade community to develop relief mechanisms on a case-by-case basis to facilitate the timely clearance of critical cargo (*e.g.*, extension of certain administrative deadlines).

Question. Which countries have been most and least helpful in terms of intercepting these products before they reach the United States?

Answer. As noted above, CBP has implemented COVID-19 specific initiatives in addition to its normal IPR enforcement activity. In addition to this, CBP coordinates with international organizations such as the Organization for Economic Cooperation and Development on best practices in dealing with COVID-19-related illicit trade. Further, CBP does have in place Customs Mutual Assistance Agreements with 14 economies that assist us in jointly targeting and interdicting counterfeit goods. CBP also leverages our network of CBP and ICE attachés to facilitate the coordination with these economies on joint operations and customs procedures. An example of some of this cooperative work can be seen in the joint operation, Operation Stolen Promise, where CBP has worked with ICE HSI on to seize and interdict illicit COVID-19-related goods. For more publicly available information and seizure statistics on Operation Stolen Promise, please visit <https://www.ice.gov/topics/operation-stolen-promise>.

COORDINATION WITH FDA

Question. To what extent do you coordinate with the Food and Drug Administration to prioritize your scarce resources to seize the most dangerous types of drugs and products?

Answer. To enhance collaboration between CBP and other U.S. Government agencies including the FDA, the CTAC was established in 2009 and is located within CBP's Office of Trade. The CTAC serves as a fusion center where CBP, FDA, and other participating personnel are co-located at a single site, sharing targeting resources and expertise to achieve the common mission of protecting the American public. The CTAC enhances CBP and FDA's ability to streamline national trade targeting efforts and coordinate among the participating agencies. This includes sharing critical import safety information and best practices, reducing duplicated targeting/examinations across agencies, and serving as a central point of response for import safety events of interest to FDA, CBP, and other agencies present. The mission of the CTAC is in line with the President's Food Safety Working Group, which

calls for agencies with an interest/authority in import safety to coordinate efforts and resources, and focuses on the core principles of prevention, surveillance, and response. Through a unique memorandum of understanding, agencies at CTAC are able to share information and systems access to conduct joint import safety targeting at the national level.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

FORCED LABOR PROGRAMS

Question. It is well-documented that the Chinese Government has pursued systemic policies to eradicate the culture and religion of the Uyghurs. Reports indicate that tens of thousands of Uyghurs are subject to forced labor conditions in the Xinjiang Province as part of this Chinese Government policy. The Australian Strategic Policy Institute (ASPI) identified 27 factories in the province that contribute to the supply chain of dozens of well-known brands, including Nike, Apple, H&M, and others. CBP has issued two withhold release orders (WRO) for hair products from producers in the Xinjiang Province on May 1, 2020 and June 17, 2020, but other imports from Xinjiang Province do not appear to be covered by WROs.

Does DHS believe products, including products from the above-mentioned brands, are being imported to the U.S. that were made with Uyghur forced labor?

Answer. DHS is committed to enforcing against the People's Republic of China's serious human rights abuses, including forced labor, against Uyghurs and other ethnic and religious minorities. Both CBP and ICE are receiving and reviewing information on forced labor in China. ICE cannot comment on ongoing criminal investigations. Importing goods produced with forced labor is a violation of Federal law, and companies and individuals may face administrative, civil, and criminal consequences.

DHS, CBP, and ICE are committed to working with the interagency, business, and civil society communities to identify and stop forced labor-derived goods from entering the United States. Information is widely available that detail the People's Republic of China's use of forced and prison labor in China. Tracing goods produced with forced labor in China to the United States is challenging due to limitations regarding supply chain transparency, availability of information, and accuracy of reporting. However, DHS and CBP are committed to working with the interagency, business, and civil society communities to identify and stop forced labor-derived goods from entering the United States.

DHS along with U.S. Departments of State, Treasury, and Commerce published a Xinjiang Supply Chain and Business Advisory, warning businesses of reputational, economic, and legal risks of involvement with entities engaged in forced labor and other human rights abuses in Xinjiang. Additionally, in September 2020, CBP announced five new WROs against entities operating in or connected to Xinjiang, covering an array of products. Linking entities that use forced labor to U.S. importers is difficult. Of the 13 WROs CBP issued this fiscal year, 9 were issued to detain products from China. Eight were specific to the Xinjiang region.

Question. What actions is DHS taking to address Chinese Government-mandated forced labor among the Uyghurs and to prevent imports produced with forced labor from entering the U.S. market?

Answer. CBP continues to investigate allegations of forced labor in the XUAR and elsewhere in China. CBP will pursue enforcement action where evidence reasonably indicates that goods from China manufactured with forced labor are imported to the United States. CBP has prioritized allegations focused in the XUAR and China as a whole. As noted above, of the thirteen WROs CBP issued this fiscal year, nine were issued to detain products from China. Eight were specific to the Xinjiang region. CBP continues to review additional allegations surrounding the region.

COMMUNICATIONS WITH RETAILERS

Question. Has DHS communicated with any of the retailers named in the ASPI report regarding the possible presence of Uyghur forced labor in their supply chains? If so, please describe the nature of those communications.

Answer. DHS along with the U.S. Departments of State, Treasury, and Commerce published a Xinjiang Supply Chain and Business Advisory, warning businesses of reputational, economic, and legal risks of involvement with entities engaged in

forced labor and other human rights abuses in Xinjiang. Linking entities that use forced labor to U.S. importers is difficult. CBP welcomes any information businesses, or any member of the public, wish to share about allegations of forced labor in the XUAR and elsewhere in China.

FORCED LABOR PROGRAMS

Question. Recent reports have also indicated the use of Uyghur forced labor in medical equipment and personal protective equipment supply chains.

Is DHS actively investigating the presence of forced labor, including Uyghur forced labor, in personal protective equipment supply chains? If so, please describe those actions.

Answer. CBP is aware of the allegations about PPE manufactured under forced labor conditions by Chinese companies. CBP will pursue enforcement action where evidence reasonably indicates that goods from China are manufactured with forced labor imported to the United States. On July 15, 2020, CBP issued a WRO to U.S. ports of entry to detain shipments of disposable rubber gloves from a Malaysian manufacturer for the use of forced labor.

Question. Has DHS blocked any shipments of medical equipment or PPE believed to have been made with Uyghur forced labor?

Answer. CBP has not yet issued a WRO to U.S. ports of entry to detain shipments of medical equipment believed to have been made with Uyghur forced labor.

Question. Please describe all actions DHS is taking to address Uyghur forced labor in medical equipment and PPE supply chains.

Answer. CBP continues to investigate allegations of forced labor in the XUAR and elsewhere in China. While CBP has taken a number of enforcement actions against violators in Xinjiang, the we will continue pursue enforcement action where evidence reasonably indicates that other goods from China, including medical equipment and PPE, are manufactured with forced labor destined for the U.S.

QUESTIONS SUBMITTED BY HON. CATHERINE CORTEZ MASTO

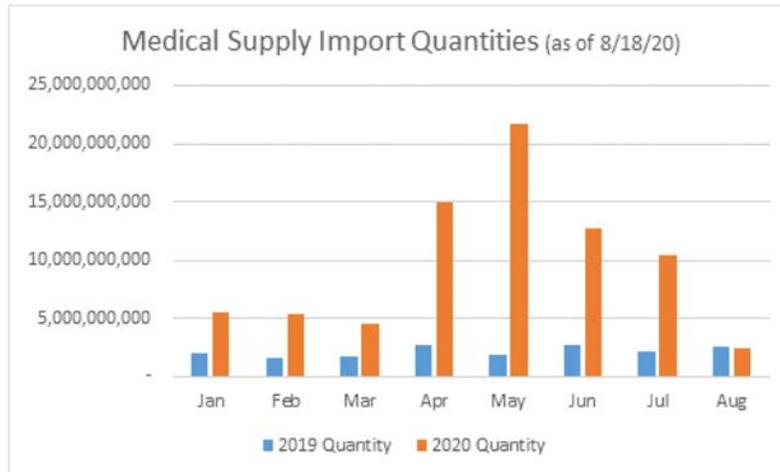
MEDICAL COMMODITIES SURGE

Question. In your testimony you describe the surge in demand for medical commodities specifically that import quantities increased by 227 percent in April alone. How does that compare to what you were seeing in March or even February?

Answer. Compared to data from the same period in 2019, import quantities for medical commodities began to increase in January—March, but rose much more dramatically in April 2020. Import quantities peaked in May 2020, and though still higher than the same periods in 2019, have subsided in June and July. April import quantities were 227 percent higher than quantities in March 2020. May 2020 quantities were 46 percent higher than April 2020.

Question. When did the U.S. demand begin to surge and has it subsided?

Answer. Compared to 2019 data, import volumes in January and February were higher than 2019, but increased dramatically in April and May. While still higher than 2019 totals, medical supply import quantities have begun to decrease, beginning in June.



PROJECT AIRBRIDGE DISTRIBUTIONS

Question. PPE that came through via Project Airbridge appears to have been distributed directly to health care providers, which circumvented the State's role as the resource coordinator. What efforts were undertaken to make sure that Governors were made aware of those distributions so that they could plan accordingly?

Answer. FEMA and HHS established the Supply Chain Stabilization Task Force to address the limited supply of critical protective and life-saving equipment during the COVID-19 pandemic response. Project Airbridge was a Task Force initiative created to shorten the amount of time it takes for U.S. medical supply distributors to bring PPE and other critical medical supplies into the U.S. CBP defers to FEMA and HHS to describe the Task Force's efforts in informing governors of Project Airbridge distributions.

PROJECT AIRBRIDGE REACTIVATION

Question. You noted in your testimony that Project Airbridge "concluded on July 1st, but retains the ability to be reactivated in accordance with shifting conditions." What specific conditions would trigger a reactivation?

Answer. CBP defers to FEMA and HHS regarding what conditions would trigger the reactivation of Project Airbridge. However, CBP stands ready to assist should the United States have a future emergent need for critical PPE due to the COVID-19 pandemic.

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

This week the Finance Committee will hold two hearings looking at why State governments and health-care providers have struggled to get the PPE and gear they need to fight the coronavirus.

Some members want this to be all about counterfeits and China. In my view, that story is way off the mark. If you want to know what's contributing most to the PPE shortage, you have to start with Donald Trump shirking his responsibility to lead, causing States and hospitals to compete against each other for supplies they need, and exposing them to scammers on the PPE gray market.

From the very beginning to this day, the President is blowing off his number one responsibility, which is to keep Americans safe. The pandemic has claimed 150,000 American lives and counting, but instead of focusing on that, the President is launching paramilitary occupations of American cities, including my hometown of

Portland. It's all a big campaign-season deflection from the enormous human and economic toll the pandemic is taking.

So Oregon is a perfect example of how the Trump administration's priorities are totally out of whack. Let me explain why. Back in the spring, the President was in full-on denial mode that he was responsible for helping our doctors and nurses and caregivers and other front-line workers find the PPE and other equipment they needed.

In mid-March, during one of his infamous coronavirus press briefings, he said the Federal Government is, quote, "not a shipping clerk" and that when it came to acquiring PPE, quote, "Governors are supposed to be doing it."

His disinterest in leading any kind of coordinated effort to acquire and distribute PPE forced the States to compete against each other on the open market. It gave room for a whole lot of sketchy suppliers and scam artists to rip off the American taxpayer and endanger front-line public health workers with unsafe and sub-standard PPE.

The State of Oregon, for example, purchased close to 1 million N95 masks from a supplier in China. After those masks arrived, they were de-certified because they could not pass a key safety screening. The U.S. agency that tests respirators, NIOSH, now says that some of the Chinese respirators they rejected could have been counterfeit, but no one knows for sure.

The fact that Oregon, like so many other States and medical providers, had to go out on its own and buy critical safety equipment in the middle of a global pandemic is a disgrace. And the pandemic is continuing to rage there. But Donald Trump isn't trying to find new ways to help Oregon deal with this pandemic.

Instead, he is terrorizing my friends and neighbors in Portland with a secret police force of hundreds of paramilitary units. Night after night, they have tear-gassed a "Wall of Moms," including my friend Sharon Meieran, a county Commissioner and ER doc who was out protesting peacefully and was gassed without provocation. They've shot peaceful protesters with impact munitions that are unquestionably capable of killing somebody. They have snatched people off the streets into unmarked vans, holding and interrogating them without justification or charges. Trump is deploying these forces to other cities. He wants to take this violence nationwide.

So what's happened in Oregon over the last few weeks and months is just one example of how Donald Trump is neglecting his responsibilities when it comes to the pandemic and abusing his office to try to get reelected.

He ought to be attacking this virus, not peaceful protesters in my hometown. And then he could actually contribute to the effort to get PPE into the hands of all the Americans who need it.

So there's a lot to talk about today. I want to thank our witnesses for joining the committee. They are a group of career officials—not political appointees—from agencies within the Department of Homeland Security. I wish the people who ran that department shared their focus on fighting the pandemic instead of using their authority to abuse Portlanders.

I also want to thank Chairman Grassley for working with us to arrange the second hearing on Thursday, when the committee will be able to speak with representatives from the medical community, including the head of the American Nurses Association. They'll also have important testimony for the committee.

COMMUNICATION

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Statement of Michael G. Bindner

Chairman Grassley and Ranking Member Wyden, thank you for the opportunity to submit these comments for the record to the Committee. I will not pull any punches on how bad things are.

This crisis is worse than you think. For whatever reason, the Coronavirus Task Force has ignored the first round of symptoms of this ailment. In my experience, it begins as a cold with heavy product. Bad timing made many sufferers believe that they were merely suffering from hay fever. There is then a week of dormancy. If you assume that exposure occurs 2 weeks prior to the first symptoms, there are 4 weeks, rather than 2, before SARS symptoms are manifested, including fever, fatigue from low oxygen levels and fatigue from the manufacture of immunity (which feels like a gut punch over a 2-week period). The CDC has just added nasal symptoms to the list, but has not yet emphasized their role in starting transmission.

In addition to masking, patients must quarantine from the first productive sneeze and stay isolated for 3 weeks or until the SARS and fatigue symptoms have passed, whichever is later. Every asymptomatic adult in the household must be quarantined until 3 weeks after everyone with symptoms has completed their quarantine. A society-wide shutdown is not required if this discipline is kept, both here and abroad.

Most nations that shut down merely guaranteed a second wave. There are people who will get sick no matter what is done, usually those with degraded immune systems due to fastidious cleaning prior to the pandemic. Young people who vape are also at high risk. The only way to assure the international supply chain is not interrupted is to limit quarantine to households where someone has nasal symptoms. The alternative is the supply chain coming to a screeching halt.

The following comments are from those submitted to the Ways and Means Subcommittee on Trade (which were excluded from Part 2 of this hearing).

Supply chains are global, and many nations who have controlled the virus by shutting down the economy rather than tailored quarantines will quickly find that many with less robust immune systems will get very sick when it opens. There will be a second wave in these nations, and a third, and a fourth. The supply chain will be stressed, if not stopped, even if draconian openings and closings can be imposed in China.

Draconian measures may be efficient, but they may add a different kind of fever, one that the regime will likely underestimate. Revolution kills production lines once people have too much. China, Inc. may not be as efficient a partner in a post-revolutionary future. Workers with more freedom to bargain and vote will want more stuff, which means higher prices here. Higher prices mean higher wages will be required, but jobs will come back as the economy changes.

Current trade policy is the wrong way to go about long-term change, especially when led by an irresponsible actor. Let me restate what we have previously written from Trade Policy comments:

Trade negotiations with China . . . have taken on the character of economic gunboat diplomacy, but without the Navy. These occur because the

President is ill-equipped by his background as a businessman to work cooperatively, which is the essence of governance in a free society. He has a freer hand in trade negotiations. Sadly, his experience as a CEO has not served the nation well. The modus operandi of most executives is to break things in order to be seen fixing them. This must stop. The public is not amused, including the Chamber of Commerce, farmers and the stock and commodity markets.

Today's witnesses are not likely to say their boss is a vainglorious idiot, so allow me to. It is well known that in this administration, professional diplomatic expertise is not valued. Mr. Trump prefers to shoot from the lip. The incompetence of this President is tragic for our ongoing trade policy, which relies on a high degree of professionalism and careful work over a period of several administrations.

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.

