

# **TESTIMONY OF**

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**BEFORE** 

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ON

"Part 1: Oversight of the Administration's Effort to Protect the Integrity of Our Nation's Medical Supply Chain"

July 28, 2020 Washington, DC 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 six 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 ten 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). <sup>1</sup>

<sup>1</sup> U.S. Department of Health and Human Services, "Fact Sheet: Explaining Operation Warp Speed" June 16, 2020, <a href="https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html">https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html</a> (July 17, 2020).).

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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.

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 22, CBP had identified and referred 159 export supply shipments to FEMA. Of those, 142 were subsequently cleared for export and 16 were cancelled 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 five 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 five 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. <sup>2</sup> 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 six 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 24. CBP continues to examine the medical supply chain for forced labor. On July 15, 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' 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

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<sup>&</sup>lt;sup>2</sup> 19 U.S.C. § 1307

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 website<sup>3</sup> 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 18, 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.<sup>4</sup> 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 frontlines of CBP's trade mission. CBP's dedicated frontline 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.

<sup>&</sup>lt;sup>3</sup> Imports.cbp.gov

<sup>&</sup>lt;sup>4</sup> 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-nationalemergency-authority-temporarily-extend-deadlines-certain-estimated-payments/ (July 15, 2020).