TESTIMONY OF

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BEFORE

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ON

"Protecting the Reliability of the U.S. Medical Supply Chain During the COVID-19 Pandemic"

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PREPARED TESTIMONY OF CHARLES D. JOHNSON,
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Protecting the Reliability of the U.S. Medical Supply Chain During the COVID-19 Pandemic, Part II
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Chairman Grassley, Ranking Member Wyden, and members of the Committee, thank you for the opportunity to appear before you today to discuss the major challenges and potential solutions in protecting the reliability of the U.S. medical supply chain during the COVID-19 pandemic and beyond.

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

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

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

1. First, the safety and efficacy of the PPE used to combat the COVID-19 pandemic has been compromised by opportunistic market behavior. The incredible increase our member companies have seen in counterfeit, fraudulent, and non-performing equipment is of great concern to the manufacturers of, and more importantly, the users of, PPE.

2. Second, the overall capability of the US to provide protection during this pandemic has been sorely tested. We must improve our overall preparedness to handle the remainder of the COVID-19 pandemic, but more importantly, there are improvements to preparedness that must be undertaken so that we can better respond to the next inevitable emergency.

Maintaining the Safety and Efficacy of PPE Supplied for Public Emergency Response

Standards and Conformity

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

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

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

1. Counterfeit products are marked or labeled with a known brand name and trade on the trust that the brand owner has built in the market – that their product is standardized and that it conforms to that standard, and that the user can trust that it provides the level of protection to which it attests.

2. Fraudulent products make false claims about their certifications, or the bodies that have provided testing.

3. Non-performing products either intentionally or unintentionally, do not meet the standards or certifications to which they attest.

ANSI/ISEA 125-2014: National Consensus Standard to Assure Product Legitimacy

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

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

Voluntary product standards are a hallmark of the United States system of PPE standardization, and have been incorporated into the U.S. system for PPE use in occupational safety. Some PPE, for

instance, respirators, are separately certified by government entities. In recent years, increased imports and entry of more and newer actors in the marketplace have led to both intentional, and possibly unintentional, abuse of these systems.

ISEA has previously brought these issues to the attention of various US agencies, including Department of Commerce, Customs and Border Control, and OSHA, and we will continue to explore solutions. As discussed below, the industry has seen an increase in false claims tied to standards during the COVID-19 pandemic. ISEA and its members continue to explore policy solutions for the issue of nonperforming PPE, and we recommend that this issue be addressed by future counterfeiting initiatives recommended below

Counterfeits, Fakes and Frauds

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

Role of DHS in Preventing Harmful Imports

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

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

ISEA Member Efforts to Prevent Illegitimate Imports

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

Small and medium-sized manufacturers are likely to be harmed the most by the counterfeit market. These companies have fewer resources to invest in the personnel and technology to monitor illicit activity and protect their brands. Government enforcement efforts often rely on

[1] https://www.nam.org/wp-content/uploads/2020/07/CounteringCounterfeits.vF_.pdf
[2] https://www.3m.com/3M/en_US/worker-health-safety-us/covid19/covid-fraud/?utm_medium=redirect&utm_source=vanity-url&utm_campaign=3m.com/covidfraud

information provided by brand owners, and smaller manufacturers are less able to engage with government entities responsible for enforcing their IP right and fighting against fraudulently marked products. Smaller firms are also more at risk to be driven out of business by counterfeiters. They often offer fewer products than larger counterparts, which means harm from counterfeits cannot be easily offset. Smaller firms are less able to absorb the losses that come when counterfeiters siphon off their business.

National Institute of Occupational Safety and Health, PPE Manufacturers Inform End-users of Fake or Fraudulent Respirators

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

NIOSH/NPPTL also performed filtration efficiency tests of several non-NIOSH certified respirators from China. Most exporters claim conformance to China's GB2626 standard. The results of the filtration efficiency tests show these devices removed 95-100% of the test particles. However, a few models had filtration performances below 50%, and some as low as 30%. Those with such low performance rates could be fraudulently marked as meeting the GB2626 standard. It was NIOSH's testing of respirators that led the Food and Drug Administration to cull its list of non-NIOSH respirators from China allowed for use in medical workplaces for protection from COVID-19.

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

Need for Strong Government-wide Coordination on Import Protection Efforts

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

[3] https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html

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

Online Retailer Responsibility Needed

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

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

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

China's Efforts to Prevent Fraudulent Exports

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

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

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

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

[5] https://www.sec.gov/news/press-release/2020-97

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

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

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

Direct and Sustained Support for Domestic Production

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

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

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

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

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

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

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

As Congress and the Executive Branch continue to focus on public health emergency response, **ISEA asks that legislators focus on direct and sustained support of domestic PPE**

production. All too often this industry has been flooded with orders only to see them disappear after the public health emergency is fully mitigated.

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

SNS Funding and Mandate

ISEA supports Sen. Alexander's recently introduced *Preparing for the Next Pandemic Act*, which supports long-term funding for both state and federal stockpiles. This type of long-term commitment is needed to encourage more US companies to enter the US supply market.

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

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

Tax Credits for PPE

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

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

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

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

Costs Associated with Occupational Safety and Health Training

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

International Trade Agreements

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

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

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

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

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

Add Protective Gloves and Garments into the PREP Act

The Public Readiness and Emergency Preparedness (PREP[8]) Act provides liability protection for items identified by the CDC as being essential to the response and mitigation of a public health emergency. Even though CDC recommends general-use gloves and garments to keep workers safe from harmful biological agents, these items are not included in the PREP Act.

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

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

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

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

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

Conclusion

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

- We must, as a nation, plan better and on a larger scale for future emergencies.

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

- We must ensure that American responders have continued support from the world's premier emergency response agencies for the selection and use of PPE.

- We must ensure the reliability and quality of the equipment provided.

- We must implement the public policy instruments that will ensure the supply of future equipment needs.

ISEA thanks the Committee for this opportunity to testify.

Respectfully,

Charles D. Johnson
President, ISEA