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October 2, 2020

The Honorable Lisa Barton
Secretary
U.S. International Trade Commission
500 E Street SW
Washington, DC 20436

Re: Investigation No. 332-580: COVID-19 Related Goods: The Industry, Market, Trade and Supply Chain Challenges

Dear Secretary Barton:

On behalf of the International Safety Equipment Association (ISEA), and pursuant to the above-referenced USITC investigation, ISEA hereby submits the attached comments for the Commission's consideration.

Thank you.

Respectively submitted,

Alberto Goetzl
Seneca Creek Associates, LLC on behalf of ISEA

October 2, 2020

Lisa R. Barton
Secretary
U.S. International Trade Commission
500 E. St., SW
Washington, DC20436

RE: Investigation No. 332-580: COVID-19 Related Goods: The U.S. Industry, Market, Trade, and Supply Chain Challenges

Dear Secretary Barton:

The International Safety Equipment Association (ISEA) is pleased to provide these comments pertaining to the above-referenced investigation. 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. Our members manufacture, import, and/or supply such products as hard hats, safety vests and harnesses, as well as COVID-19-related products that are the focus of the Commission's current 332 investigation. These products include: *disposable respirators, reusable respirators, face shields and protective eyewear, non-medical gloves, and protective garments*. Over the years, ISEA member companies have responded to national emergencies and disasters of all kinds, from the terrorist attacks on Sept 11, 2001 to wildfire, to hurricanes, and to public health emergencies, including COVID-19. In these comments, we provide additional information about PPE products, supply issues, and needs going forward.

Disposable Respirators

The N95 is a category of disposable respirators that are technically known as filtering facepiece respirators, or FFRs. In this class of respirator, the facepiece is made of filtering material. For these respirators, NIOSH tests the filtration efficiency, and the inhalation and exhalation resistance of these devices. The respirator must be able to filter out 95 percent of airborne particulates. NIOSH also reviews the applicant's quality control program. To be sold as an N95 respirator, it has to be certified as such by NIOSH.

ISEA member companies that manufacture respiratory protection are 3M, Honeywell, Drager, Kimberly Clark Professional, Moldex, and Medicom There are also new entrants into the market, and new US producers. For example, Thermopore, a US-based manufacturer of porous plastics, recently received NIOSH certification for its new FFRs. In addition, other US manufacturers have applications pending before NIOSH.

Production data is generally not public. However, in public statements, 3M has indicated that, by October, it will produce 96 million respirators per month in the United States, for a total of 1.15 billion units per year. Combined, ISEA's filtering facepiece respirator manufacturers will provide at least 1.35 billion N95 respirators per year when production is at full capacity. ISEA believes 2020 production of this type of respirator will be about 3 times greater than last year.

It is also likely that demand for filtering facepiece respirators will remain strong going forward. The demand from replenishing federal and state stockpiles, filling new stockpiling requirements, and meeting COVID-19 and existing workplace respirator needs will consume all that U.S. manufacturers can produce.

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Personal Protective Equipment (PPE) is a global business and the U.S. imports N95 respirators from several countries, most notably from China. China accounts for the lion's share of N95 imports, evidenced by imports classified in HTS 6307.90.9845, an HTS statistical annotation created in July of this year.

ISEA members report that curtailments in Chinese exports of disposable respirators significantly affected the supply in the United States. As COVID-19 began in the U.S., imports from China essentially stopped and only restarted slowly in April. Obviously, China had very high domestic demand to address its own COVID-19 infections. However, there were other reasons that Chinese exports slowed. The Chinese government, not the companies, controlled the trade deals for respiratory protection. In an effort to stop fake and fraudulent products from being exported, the Chinese government began requiring individual labeling and packaging. That slowed deliveries and, as a result, the unit cost of respirators also increased. In fact, some U.S. companies are still unable to obtain NIOSH certified respirators from manufacturers in China.

Reusable Respirators

There are three types of reusable respirators: half-mask respirators, full-facepiece respirators and Powered Air Purifying Respirators (PAPRs).

Half-mask air purifying respirators, known also as "elastomeric" respirators because they are made of elastomeric rubber, have replaceable filters that provide a wide array of protection. They fit tightly over a wearer's face and mouth.

Full facepiece respirators, are also a type of air purifying respirator. These are similar to half-mask respirators except that they also have a clear facepiece that enables full eye and face protection. Elastomeric and full facepiece respirators can be used in health-care settings. In fact, NIOSH has recently asked for comments about how the use of reusable respirators can be optimized in healthcare.

Finally, Powered Air Purifying Respirators (PAPRs) have a power unit to move air through a filtration mechanism. PAPRs come in a wide variety of shapes and sizes and are also experiencing a greater acceptance in the hospital workplace. Locally, the University of Maryland Hospital uses PAPRs.

An important point to make here is that reusable respirators can temper the demand for disposable respirators, such as N95s, and have generally experienced fewer production bottlenecks or shipment delays during the pandemic because they are largely made in the U.S.

Face Shields and Protective Eyewear

Face shields and protective eyewear, including side shields for eyewear,[1] have become another important product for protection against the spread of COVID-19. Accurate statistics on demand and production of face shields are unavailable, but ISEA members believe that demand for face shields tripled during the first half of 2020 compared to 2019. At least one ISEA member that manufactures face shields informed us that they encountered workforce shortages during the pandemic.

[1] For an example, see https://www.sideshield.com/

Non-Medical Gloves

ISEA represents suppliers of non-medical gloves. These are typically nitrile or latex gloves that are commonly used in an assortment of applications, from food service to automotive repair. Non-medical gloves are distinguished from medical gloves by virtue of the standards that are set by FDA. Medical gloves must meet FDA standards related to leak resistance, tear resistance and biocompatibility. However, non-medical nitrile or latex gloves can, and are often, used in non-medical settings where there is a risk of COVID-19 spread. Food handling and cleaning are typical uses for non-medical gloves. Demand for nitrile and latex non-medical gloves surged this year. Based upon conversations with member companies, we estimate demand increased by 600 percent.

Protective Garments

Finally, protective garments take various forms, including those specifically approved by the FDA for medical uses. The FDA website provides descriptions of the types of medical gowns that are approved in situations based on levels of risk.[2] However, during the pandemic, healthcare employers and workers have clearly gone outside the normal medical supply chain to procure protective garments that would normally be used in other occupational settings. We are unaware of data that would be instructive of the total demand for all kinds of protective garments used during the pandemic. Given their low prices, most disposable protective garments are made outside of the United States. The competitive nature of the industrial markets into which these garments are normally sold suggests that higher prices, associated with domestic manufacturing, would not likely be accepted.

Counterfeits, Fakes and Frauds

ISEA recommends that the Commission assess the effects of an increased amount of fake, fraudulent and counterfeit COVID-19-related PPE as part of this investigation. ISEA members have long been concerned about the risk to safety and health from products that are mislabeled, misrepresented, or are counterfeit. This type of illicit action is often the work of international criminal networks.[3]

Customs and Border Patrol (CBP) and Homeland Security Investigations (HSI) of the Department of Homeland Security (DHS) have taken a number of steps to stop fraudulently marked and counterfeit COVID-19-related products from entering the United States. ISEA understands that, while most seizures during the COVID-19 pandemic have been of illicit respirators and surgical masks, additional types of PPE interdicted by federal authorities have included 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.

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 been conducting two efforts to provide safety equipment purchasers with clear information on key products. First, for a number of years, NIOSH has been posting respirators fraudulently marked as claiming to be a NIOSH-certified

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[2] https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns#g1

[3] Jay Kennedy, "Buyer Beware: Counterfeit markets can flourish during a public health crisis," THE CONVERSATION (March 26, 2020), https://theconversation.com/buyer-beware-counterfeit-markets-can-flourish-during-a-public-health-crisis-134492; Europol, How Criminals Profit From the Covid-19 Pandemic (Mar. 27, 2020), https://www.europol.europa.eu/newsroom/news/how-criminalsprofit-covid-19-pandemic.

product.[4] Second, NIOSH/NPPTL has recently begun performing filtration efficiency tests of several non-NIOSH certified respirators from China that claim conformance to China's GB2626 standard.[5] Some of these show low filtration efficiency.

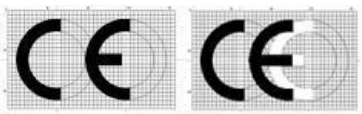
Large companies report that they have successfully gone after and forced the removal of fraudulent internet addresses, e-commerce offerings, and social media posts. However, small and medium-sized manufacturers with fewer resources are less able to engage with government entities responsible for enforcing intellectual property rights and fighting against fraudulently marked products. They are likely to be harmed the most by the counterfeit market.

The increased demand for PPE, including non-medical gloves, has led to a rise in elaborate fraud schemes seeking to take advantage of customers and end-users. These deceptive practices promise counterfeit versions of PPE with fraudulent product registrations, certificates, and/or test reports that do not meet manufacturer's quality standards. These scams might also use social engineering techniques, including "spoofing," by fraudulently using company employee names, logos, brands and/or look-alike company emails. These practices frequently involve the non-delivery of PPE after a buyer has remitted payment to the fraudsters. Such cases often involve criminals promising to deliver large quantities of PPE that they do not actually possess.

The Federal Bureau of Investigation (FBI) has disclosed a number of recent incidents where state government agencies have fallen victim to PPE fraud schemes in which agencies have provided funds to fraudulent brokers and sellers prior to receiving the merchandise. The FBI claims that the perpetrators include both domestic and foreign entities. In many of the cases, by the time the purchasers became suspicious, much of their funds had already been transferred beyond the reach of U.S. law enforcement and were therefore unrecoverable.

While illicit PPE has clearly been a problem during the pandemic, fake and counterfeit goods are an issue of wider concern. The National Association of Manufacturers (NAM) addressed the issue recently in "Countering Counterfeits: The Real Threat of Fake Products," and has proposed initiatives to battle against counterfeit goods, across the board.[6]

Certain types of labels and marks cause confusion in the marketplace. A good example is the "China Export" mark that is substantially similar to the official European "CE" marking, which demonstrates a product has met the relevant and strict EU standards. The EU "CE" marking is beneficial because it signifies conformance to certain standards, while the Chinese "CE" market merely means that the product was manufactured in China:



CE Mark China Export

[4] https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html
[5] https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html
[6] https://www.nam.org/wp-content/uploads/2020/07/CounteringCounterfeits.vF .pdf

Different standards for PPE in China also cause some confusion. In one case we are aware of, China's Ministry of Commerce officials prevented the export of protective garments because they did not claim to meet a specific Chinese standard. However, these particular products were destined for the U.S. market where there is no government standard for them. 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. This effort was successful. Nonetheless, fake, fraudulent and counterfeit products from China continue to be a concern for ISEA members and others alike.

Efforts that the ISEA and its members have taken to prevent illegitimate imports include: working cooperatively with on-line retailers to remove counterfeit products from their sites; participating in the Coalition for a Secure and Transparent Internet, which has been leading the charge on WHOIS data transparency and access;[7] and joining 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. 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.[8]

Buy America and the Trade Agreements Act (TAA)

At the September 23rd hearing, there was considerable discussion about using "Buy America" provisions or mandates to foster U.S.-produced PPE supplies. ISEA does not believe that the failure of the federal government to properly plan for a pandemic should be used as a reason to change aspects of our international trading system that has, in fact, allowed US companies to efficiently supply high-quality, price-competitive products to end-users both domestically and internationally.

PPE is included in the Trade Agreements Act (TAA) and some organizations have proposed restricting the trade flows that the TAA enables. Under the TAA, U.S. companies are able to source from a list of 60 nations that have all agreed to economically cooperate with each other. ISEA believes PPE should not be removed from the Trade Agreements Act (TAA). If modified, key TAA-sourced components could very well become more difficult to source and prices of PPE would likely rise. Moreover, economic cooperation stemming from the TAA is well-known to have strategic benefits that advance our international policy objectives. Trade agreements also allow nations to work cooperatively to stop fake, fraudulent and counterfeit goods from entering the global market place.

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[7] www.secureandtransparent.org

[8] 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. Law enforcement and IP holders have effectively been blocked from accessing critical WHOIS data (domain name registrations) that would support efforts to reduce cybercrime. ICANN's process for trying to resolve the issues related to WHOIS data access (officially the ICANN Expedited Policy Development Process) has concluded and is widely known as a failure to all parties except those set to profit from blocking access to WHOIS data, domain name registries and registrars. This is further evidence that Congress must act to protect the security and transparency of the open internet and the businesses and consumers who rely on it. See discussion at: https://cybertechaccord.org/whois-the-process-grinds-forward-sort-of-no-relief-for-cybersecurity-pros-is-in-sight/ and http://www.circleid.com/posts/20200922-a-failed-whois-policy/.

Ensuring Adequate Supply of PPE

The single most significant factor affecting the market and availability of PPE products during the first half of 2020 was, and continues to be, the surge in demand. Unprecedented demand materialized very quickly as the pandemic emerged and supply chains were overwhelmed. It took time for manufacturers and distributers to adjust and adapt. Orders were coming in from all over, from private and public entities, and, given limited inventories and finite supplies of product in the pipeline, fulfillment was a major challenge. There was considerable confusion and market disruption. The pandemic has underscored the need for better forecasting of demand and better preparedness associated with large scale emergencies. Among the policies ISEA is advocating to better accommodate PPE demand during emergencies are:

- Provide FEMA and/or HHS with authority during a public health emergency to gather data from state and local governments, healthcare providers, and suppliers regarding the supply, use, and demand for PPE. This would help ensure optimal distribution decisions can be made based on real-time data;

- Use predictable and longer-term contracts to govern public purchasing of PPE. All too often this industry has been flooded with orders only to see them disappear after the public health emergency is fully mitigated;

- Implement more comprehensive quantitative planning for the Strategic National Stockpile (SNS). The SNS needs a centralized planning process that develops demand scenarios, prioritizes needs, and then establishes institutionalized supply solutions to meet those demands;

- Recognize that PPE supply chains are global in nature. Unnecessarily restricting the origin of PPE to augment the SNS would increase costs;

- Increase funding for both state and federal stockpiles. Enact the “Preparing for the Next Pandemic Act,” which supports long-term funding for PPE stockpiles. This type of long-term commitment is needed to encourage more US companies to enter the US supply market;

- Ensure that non-medical machine-washable fabric face coverings qualify for procurement tax deductions. Non-medical fabric face-coverings are essential in every-day life during COVID-19, but these items are not traditional PPE, and they are not sanitary products;

- Include general-use gloves and garments in the liability protection provisions of the Public Readiness and Emergency Preparedness (PREP) Act when used for public health purposes. The (PREP) Act provides liability protection for items identified by the CDC as being essential to the response and mitigation of a public health emergency. These products keep workers safe from harmful biological agents, but they are not currently covered under the legislation or its rules;

- Employ the Defense Production Act (DPA) as a way of aiding US manufacturers and the federal government’s ability to provide necessary equipment and products. However, the DPA should be used as a cooperative private-public partnership and in a considered, careful fashion. The diversion of components needed by a non-participating company to a DPA manufacturer can offset the DPA’s benefits.

ISEA would caution and oppose most restrictions on international trade of PPE products. As mentioned earlier in these comments, PPE is globally sourced and prices are competitive. Trade constraints tend to

disrupt, not facilitate, supply chains and often result in retaliatory measures that harm U.S. producers. Even restrictions on exports, such as FEMA's ban on exports of respirators and filters, may increase domestic supplies in the short-term, but will have long-term consequences as foreign customers seek alternative sources.

The key to addressing any future surges in PPE demand comes down to augmenting the SNS and doing a much better job in anticipating how and where demand will emanate so that proper planning can be done to accommodate those needs. The goal we all share is to get PPE into the hands of people who need it, when they need it, and ensure that it is safe and effective. We are confident that the USTIC's current investigation will provide needed information to the U.S. Congress and the public to help meet that goal.

ISEA appreciates the opportunity to provide these comments. If you have any questions, please free to contact me at 703-795-6064.

Sincerely,

Daniel Glucksman
Director, Public Affairs

Summary for Inclusion in the Report:
International Safety Equipment Association (ISEA)

The International Safety Equipment Association (ISEA) represents U.S. companies that design, test, manufacture and supply personal protective and safety equipment. ISEA members produce and distribute personal protective equipment (PPE) used in many occupations, including healthcare. ISEA members produce and supply COVID-19-related products such as disposable respirators, reusable respirators, face shields and protective eyewear, non-medical gloves, and protective garments. Among disposable respirators, ISEA members produce the majority of N95 masks made and distributed in the United States. As the pandemic developed, Chinese domestic demand and export restrictions caused bottlenecks in imported supplies of PPE, including N95 masks.

Reusable respirators, including half-mask respirators, full-facepiece respirators and Powered Air Purifying Respirators (PAPRs), have also been crucially important during the COVID-19 response. Reusable respirators are largely made in the United States and can alleviate the demand for disposable respirators, such as N95s. They have generally experienced fewer production bottlenecks or shipment delays during the pandemic.

The safety equipment industry is global in nature. ISEA believes that better planning, not major changes to our international trading system involving PPE, would improve a pandemic response. PPE is included in the Trade Agreements Act (TAA) and some organizations have proposed restricting the trade flows that the TAA enables. If modified, key TAA-sourced components could very well become more difficult to source and prices of PPE would likely rise. Moreover, economic cooperation stemming from the TAA is well-known to have strategic benefits that advance our international policy objectives.

ISEA fully supports a plan by the current management team at the Strategic National Stockpile, or SNS, to create a data system that collects the public health community's demand for a wide array of needed items, and in turn shares that data with the supplier community. This type of system will allow suppliers and end-users alike to avoid a situation in which competing interests result in the misallocation of needed supplies.

The use of the Defense Production Act (DPA) has been effective. However, the DPA should be invoked with industry cooperation. Absent good planning, the DPA could (and has) shifted the supply of needed components from one company to another.

Finally, an area of significant concern is the rise of counterfeit products and fraudulent schemes by bad actors taking advantage of the desperate demand for PPE. Frequently, these counterfeit products do not meet industry or government standards, and they put users at risk of injury, sickness, or death. Further, the fraudulent schemes typically involve demands for upfront payment from would-be consumers and promises to deliver large quantities of PPE that the fraudsters do not actually possess. Both private and public efforts are on-going to curtail counterfeiting, fraudulent claims, and faked performance, but more needs to be done.

There are certainly lessons to be learned from the current pandemic experience. The single biggest factor affecting the market and availability for PPE products was, and continues to be, the surge in demand. Because the unprecedented demand for essentially every COVID-19-related product materialized very quickly, supply chains were overwhelmed. That situation revealed the need for better preparedness planning going forward.