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INTERNATIONAL BUSINESS ALERT

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Legal issues to be aware of when importing personal protective equipment during COVID-19

With the continuing COVID-19 pandemic and the increasing need for personal protective equipment (PPE) including respirators, gloves, goggles and glasses, gowns and thermometers, businesses are looking overseas for PPE to satisfy U.S. domestic needs. On April 3, 2020, the U.S. Centers for Disease Control and Prevention (CDC) recommended that people wear a cloth face covering in public settings where other social distancing measures are difficult to maintain – especially in areas of significant community-based transmission. The governor of Pennsylvania signed an order effective April 19, 2020, directing employers to provide masks to employees and make it a mandatory requirement that employees wear masks while at their work sites. Further, the order requires that all customers wear masks while on employers' premises, and deny entry to individuals not wearing masks. The governor of New York signed a similar order on April 15, 2020, requiring all New Yorkers to wear masks or have their mouth and nose covered while out in public. With those updated guidelines and people returning to work, it is expected that the PPE demand will continue to increase as companies are now preparing to resume operation amid COVID-19. As companies continue to import PPE from overseas, companies should be aware of the following legal issues and plan accordingly.

Know your suppliers

One fundamental principle for importing PPE from overseas is to ensure you have a credible supplier and reliable referral sources. Numerous investigations, complaints or charges have been filed involving alleged fraudulent transactions or defective products. In addition, many countries have license and qualification requirements for PPE manufacturing, and

Information about COVID-19 and its impact on local, state and federal levels is changing rapidly. This article may not reflect updates to news, executive orders, legislation and regulations made after its publication date. Visit our COVID-19 resource page to find the most current information.

products from unlicensed and unqualified manufacturers may not be exported. For example, for PPE to be considered as a medical product by the National Medical Product Administration in China, China requires exports from manufacturers who have a medical device operation license within the scope of business and with the proper import and export license. Therefore, while it is understandable that companies need to import PPE to the U.S. in a timely fashion, it is strongly recommended that companies perform all necessary due diligence – including engagement of local counsel if appropriate – to help to mitigate the aforementioned risks.

Tariff exemptions, exclusions and delayed payment available

To better meet the growing domestic needs, the United States Trade Representatives (USTR) has issued several notices exempting certain medical and sanitary products of Chinese origin from Section 301 tariffs. Those exempted products include soap, laboratory equipment, sanitary articles (e.g., face masks, hand sanitizer, disinfectant wipes and sprays), rubber gloves, surgical drapes, non-woven apparel designed for use in hospitals, certain other medical wares, certain bowls of molded plastics and certain cold packs and protective articles. The list of the exempted products can be found in the Annex of the March 10 Notice, March 17 Notice in the Federal Register. Those exemptions are retroactive in nature such that entities can seek refunds of the Section 301 duties that they have paid on the excluded products dating back to September 1, 2019. The combined exemptions will entitle exemption of the subject products from Section 301 tariffs until September 1, 2020.

In addition to the above exemptions, the USTR is now accepting new Section 301 exclusion requests relating to other products of Chinese origin not falling within the above exemptions that can be used in the battle against COVID-19, including products with previously denied or currently pending exclusion requests, as well as for products for which requests have not been filed. Exclusion requests should identify the particular product of concern and its applicable Harmonized Tariff Schedule of the United States (HTSUS) number and should explain how the product can be used to respond to the COVID-19 outbreak. Exclusion requests can be submitted through the online portal at regulations.gov by searching the docket number USTR–2020–0014, but the deadline to request such exclusion ends on June 25, 2020, unless extended by the USTR.

Further to possible Section 301 duty exclusions for certain PPE and medical products imported from China, President Donald Trump signed an executive order permitting the U.S. Treasury to defer tariff payments "for importers suffering significant financial hardship because of COVID-19." The treasury has since published an interim rule permitting companies to defer paying tariffs on many imported goods during COVID-19 to provide relief to businesses. However, it is important to remember that matters are fluid and change frequently, so it is essential to check the current rule at the time of the import.

Possible FDA exemptions

To facilitate importation and help to expand the availability of PPE for use by the general public and health care professionals, the U.S. Food and Drug Administration (FDA) has relaxed the 501(k) premarket notification and clearance requirements with regard to face masks, respirators, thermometers and certain other medical products. For example, on March 24, 2020, the FDA issued an Emergency Use Authorization (EUA) for importing non-NIOSH-approved N95 respirators. Under this EUA, among other criteria, the FDA accepts marketing authorization from Australia, Brazil, Europe, Japan, Korea and Mexico who have similar standards to NIOSH. The FDA later issued an updated EUA for non-NIOSH-approved N95 respirators made in China, which makes KN95 respirators (the Chinese equivalent of the U.S. government's N95 standard) eligible for authorization if certain criteria are met, including evidence demonstrating that the respirator meets certain standards. The FDA also issued an Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised) outlining a policy to help expand the availability of general use face masks to the general public and respirators for health care professionals during this pandemic. It explains that for the duration of the pandemic, when FDA-cleared or NIOSH-approved N95 respirators are not available, the FDA generally would not object to the importation and use of respirators without an EUA. The FDA additionally issued the Guidance for Industry and Food and Drug Administration Staff: Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, which permits the importation of clinical electronic thermometers during the COVID-19 pandemic without FDA 510(k) preclearance. The FDA has further adjusted its import screening to help expedite imports of legitimate products and is continually monitoring its import systems to prevent and mitigate any potential issues. For more details on importing masks and respirators from overseas during COVID-19 under FDA's relaxed rules, please see Importing Masks and Respirators from Overseas During COVID-19 under FDA's Relaxed Rules. However, as with tariffs, these matters are fluid and change frequently, so it is essential to check the current rule at the time of the import.

Be aware of possible government prioritization and allocation

President Trump recently signed several executive orders under the Defense Production Act (DPA), 50 U.S.C. 4501 et seq. The DPA grants broad, emergency authority to the President to control national economic policy in furtherance of national defense, which includes emergency preparedness. Among other things, the DPA allows the federal government to direct private industry to accept and prioritize contracts and permits the federal government to purchase essential materials or supplies in a public emergency. In accordance with such authority, President Trump has on March 18, 2020, issued Executive Order 13909 (Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of COVID-19), in which President Trump delegated to the Secretary of the Department of

Health and Human Services (HHS) the prioritization and allocation authority under section 101 of the DPA with respect to health and medical resources needed to respond to the spread of COVID-19. It has been reported that HHS's broader effort has been to prioritize and maximize the availability of personal protective equipment for healthcare workers who are on the front lines mitigating the community spread of COVID-19. While the government is required to pay just compensation, typically at the current prevailing market price (50 U.S. Code § 4533(a)(3)), companies importing PPE must be aware of and financially prepared for the possibility that their shipment of PPE may be intercepted upon entry and not reach its intended place, nor earn its expected price. As with tariffs and FDA exemptions, this is a fluid and rapidly changing situation and companies should regularly monitor government communications on this topic.

Do not hoard

On March 23, 2020, President Trump issued an Executive Order (Preventing Hoarding of Health and Medical Resources To Respond to the Spread of COVID-19) instructing HHS and the Department of Justice (DOJ) to enforce the anti-hoarding and price gouging provisions under the DPA against those who hoard supplies of necessary health and medical resources. The HHS was specifically authorized to "prescribe conditions with respect to the accumulation of" COVID-19 related materials, "to designate any material as a scarce material," or to designate "as a material the supply of which would be threatened by persons accumulating the material either in excess of reasonable demands of business, personal, or home consumption, or for the purpose of resale at prices in excess of prevailing market prices." Following the Executive Order, the HHS published a Notice on March 25, designating the following categories of medical and health resources as "scarce" or "threatened" within the meaning of 50 U.S.C. § 4512 of the DPA, including:

- N-95 Filtering Facepiece Respirators and other types of respirators;
- Portable Ventilators;
- Drug products with active ingredient chloroquine phosphate or hydroxychloroquine HCl;
- Certain sterilization services;
- Certain disinfecting devices;
- Medical gowns or apparel and PPE coveralls; and
- PPE face masks, surgical masks, face shields and gloves.

Under Section 102 of the DPA, it is unlawful to accumulate these scarce materials at levels "in excess of the reasonable demands of business, personal, or home consumption" in a declared public emergency. 50 U.S. Code § 4512. While it is not entirely clear what is considered to be hoarding, U.S. Attorney General William Barr has explained in a White House Press Briefing that the action was aimed at "people hoarding these goods and materials on an industrial scale for the purpose of manipulating the market and ultimately driving windfall profits. If you

have a big supply of toilet paper in your house, this is not something you have to worry about. But if you are sitting on a warehouse with masks, surgical masks, you will be hearing a knock on your door." The DOJ has also established a COVID-19 Hoarding and Price Gouging Task Force to perform investigations on any alleged hoarding and price gouging activities. Violating the DPA in this manner is considered a misdemeanor for individuals and companies and could result in a fine up to $27,000.00, or up to one year imprisonment. See 50 U.S.C. § 4513.

Do not price gouge

Price gouging has both federal and state law implications. Section 102 of the DPA provides that "[i]n order to prevent hoarding, no person shall accumulate . . . for the purpose of resale at prices in excess of prevailing market prices, materials which have been designated by the President as scarce materials or materials the supply of which would be threatened by such accumulation." 50 U.S. Code § 4512. Under the above stated March 23 Executive Order and the HHS' March 25 Notice, it is illegal "for the purpose of resale [the above listed PPE] at prices in excess of prevailing market prices." The HHS and DOJ are further authorized to enforce price gouging provisions under the DPA and as mentioned above, have established a COVID-19 Hoarding and Price Gouging Task Force to perform investigations on any alleged hoarding and price gouging activities. Still, "prevailing market prices" is not defined under the DPA, and it remains to be seen what "in excess of prevailing market prices" means in the context of importing PPE from overseas. Amid increased political pressure to combat price gouging, concerns have been raised that federal enforcement agencies - primarily the DOJ and the Federal Trade Commission (FTC) – may try to stretch existing laws addressing fraud, antitrust, and deceptive advertising to additionally target businesses that advertise and sell products by taking advantage of consumer fears.

While there is no federal price gouging law, numerous states have established laws by which they can trigger protections against price gouging, which are enforced by the respective state Attorneys General. More state price gouging laws are in the works due to the COVID-19 crisis. While the various state laws differ, generally, price gouging laws (1) are triggered by a declared state of emergency, (2) apply to specified goods and services, and (3) apply when the price of those goods or services are higher after the declared state of emergency than they were at some designated point in time prior to the declaration. Some statutes apply only to fuel, others to products or services considered necessary to health and welfare and yet others include a wide range of products and services. Certain states set price gouging at a specific percentage over previous prices (often 10% or 15%), though others use more vague terms such as "excessively priced." While the benchmark period for comparing prices is always before the declared state of emergency, some states designate a specific date, whereby others use a 30-day look back period. Some state laws allow for price increases that are justified by a corresponding increase in input costs. But, that is not true for all states. Given the many differences

between the various statutes, determining whether a violation existed or whether any valid defenses exist requires a nuanced consideration of not only the specific laws involved but also the relevant industry conditions. Additionally, for states without specific price gouging laws, perceived price gouging may be prohibited by Executive Orders or attacked under the state's unfair competition laws.

Given the vagueness in the various state price gouging statutes and the fluid and changing federal environment, there is a level of risk involved in buying and selling PPE. Companies should be aware of such risks and be prepared to deal with government knocks on the door. Strategies to mitigate such risks include maintaining historical pricing data, documenting justifications for any price changes (tie pricing decisions to market factors, including actual costs), keeping track of increase in labor and material costs and implementing a process for the approval, staffing and real-time evaluations of pricing changes during a time of crisis. It is important to document the reasons for all price changes. Each of these activities will assist in defending against investigations/claims that prices were unfairly increased without good cause.

Do not price fix

Generally, companies are free to set their own prices as they see fit if those decisions are made independently. However, companies are generally prohibited from having agreements with their horizontal competitors about what prices they will charge under antitrust laws. Such agreements can be considered price fixing subject to potential criminal investigation and prosecution under federal and some state antitrust laws. Notably, the DOJ and FTC have issued a Joint Antitrust Statement Regarding COVID-19 in which they announced an expedited procedure for evaluating proposed collaborations among competitors and other businesses working to address the pandemic. The agencies committed to responding to business review requests related to COVID-19 within seven calendar days of receiving all information necessary to vet these proposals, which is significantly faster than the agencies' usual timeline of several months. The agencies also took the opportunity to remind the public of certain long-standing principles regarding situations where competitor collaboration gives rise to pro-competitive benefits. For example, sharing technical know-how, rather than company-specific data about prices, wages, outputs or costs, may be necessary to achieve the procompetitive benefits of certain collaborations. Therefore, while companies may be permitted to collaborate to better cope with COVID-19 and to provide pro-competitive benefits, companies are advised to not discuss with competitors any intention to charge emergency or other surcharges or to eliminate certain discounts, and further not to have any sort of agreement with its competitors on the price. Companies are further encouraged to make certain they have robust antitrust compliance programs and reporting and audit functioning in place to ensure compliance.

Comply with the export regulations of the country from which the PPE will be imported

Finally, it is critical that companies importing PPE satisfy the export regulations of the country from which the PPE will be imported. Each country has its own testing and certification requirements under its export regulations that must be met before PPE can be exported. For example, certain PPE might be considered regular non-medical product and certain PPE might be considered as medical product by the National Medical Products Administration in China. Non-medical devices can be exported directly by enterprises with an import and export operation license without additional certification or report requirements, but export of medical products requires the exporting enterprise to submit its business license (the business scope the includes related medical device), medical device manufacturing license, product record certificate or registration certificate, and manufacturer test report to the Chinese Custom, in addition to the requirement that the enterprise must also have an import and export operation license. Additionally, masks exported must be accompanied by a test report by one of the 46 laboratories accredited by the China National Accreditation Service for Conformity Assessment for testing of masks, otherwise the shippers will deny transportation and the masks will be rejected from export. Therefore, it is of critical importance that companies importing PPE engage local counsel in the country they are importing from to confirm they comply with the export regulations in that jurisdiction to ensure smooth export from that country.

For more information please contact Yuanyou Yang or any member of Porter Wright's International Business & Trade Practice Group.