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JUNE 11, 2020

PPE procurement considerations in light of recent DOJ criminal complaint against foreign mask manufacturer

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Since the beginning of the COVID-19 pandemic, shortages around personal protective equipment (PPE), including face masks, gowns, and gloves, have garnered significant media attention. In response to these shortages, the Food & Drug Administration (FDA), which regulates face masks, gowns, and gloves as medical devices when intended for a medical purpose, has issued a host of guidance documents, Emergency Use Authorizations (EUAs), and other statements in an effort to address the PPE shortages while ensuring the safety of the additional products permitted to be sold in the U.S. market.

In tandem, at the outset of the pandemic, the Department of Justice made clear that the government will prioritize prosecutions of fraudulent conduct taken in response to the pandemic. The FDA has issued dozens of warning letters to-date where companies or individuals allegedly have made unproven marketing claims that their products will prevent, treat, mitigate, diagnose, or cure COVID-19. And on June 5, 2020, the Department of Justice filed a criminal complaint against a Chinese manufacturer, King Year Printing and Packaging Co., Ltd. (King Year Printing), for the introduction of misbranded N95 respirators into the U.S. market.

In light of the unprecedented demand for PPE, many companies have stepped in to address the various production gaps. Despite the FDA's guidance documents and EUAs, the procurement, importation, brokering, and sale of PPE remains highly regulated, and careful consideration must be given to various legal and logistical considerations. Using takeaways from the King Year Printing criminal complaint, this alert provides key, practical considerations to assess when companies or institutions look to procure, market, sell, or use PPE from foreign or non-traditional manufacturing sources.

Overview of King Year Printing criminal complaint

The criminal complaint against King Year Printing, filed by the United States Attorney's Office for the Eastern District of New York, charged the Chinese manufacturer with the introduction of misbranded devices into interstate commerce. Specifically, the complaint stated that the product labeling for the "self-breathing filtration particle-preventive respirators . . . falsely included the

NIOSH [National Institute for Occupational Safety and Health] logo[,] despite the respirators not being NIOSH[-]approved, and 'N95' markings and a test report showing compliance with the N95 standard despite the respirators not meeting the minimum standard for N95 respirators . . ." (Paragraph 1.) The complaint alleges that King Year Printing introduced almost 500,000 such respirators into the U.S. market in April 2020. The complaint also charged King Year Product with making false statements to the United States.

Notably, the bulk of the criminal complaint contains the affidavit of a special agent of the FDA's Office of Criminal Investigations. These allegations reflect the FDA's continued work, despite the COVID-19 pandemic, to investigate, allocate resources, and root out instances of alleged fraudulent conduct. The agent's affidavit reflects work that includes "witness interviews and [the review of] other evidence, including email and text message communications, telephone toll records, and publicly[ ]available reports." (Paragraph 4.) The criminal complaint describes the alleged activities of not only King Year Printing, but also those of unnamed individuals and companies, including supply brokers and importers.[1]

The complaint further alleges that "King Year falsely labeled the Subject Respirators with the intent to defraud U.S. consumers, including medical providers and state and local governments, into believing they were buying N95 respirators approved, cleared, or otherwise authorized by the [FDA] and [NIOSH/CDC]. In fact, the Subject Respirators were neither FDA-approved, cleared, nor authorized nor NIOSH-approved. And the Subject Respirators did not perform at the promised minimum 95% filtration efficiency level. Nevertheless, the defendant King Year attempted to cover up the poor quality of the Subject Respirators in various ways—by stamping FDA and NIOSH logos on its packaging, by embroidering each Subject Respirator with the label, 'N95,' by procuring and disseminating false documents attesting to the authenticity of the Subject Respirators, by filing a false registration document claiming the masks were NIOSH-approved, and by using a fictitious corporation as its U.S. agent in registration documents filed with the FDA." (Paragraph 13.)

Practical Considerations for Sourcing PPE

1) ***Understand the type of product that is being considered for import, sale, marketing, or use and assess the applicable labeling requirements.*** Particularly with respect to face masks, the type of mask under consideration will drive the labeling requirements. Assess what the mask is and where the mask is intended to be used. Will it be used for general source control, whether in public or in a health care setting or will it be used in surgery? Is the product a non-cleared face mask, a cleared surgical mask, an N95 mask, or a non-NIOSH approved mask? Different EUAs, guidance documents, and regulatory controls apply to the

[1] "Individual-1 was a U.S. citizen residing in the PRC who brokered deals for pharmaceutical and medical products from companies located in the PRC. As COVID-19 spread in the PRC and throughout the world, Individual-1 entered the business of buying, selling, and importing PPE into the United States. Indvidiual-1 held himself out to buyers in the United States as having connection to Chinese pharmaceutical companies, medical equipment manufacturers, provincial governmental leaders, and central government ministry leaders, including the Ministry of Health." (Paragraph 6.) "Company-1 was a Utah corporation located in West Valley City, Utah. Its primary business involved the import and export of supplements and raw materials from the PRC." (Paragraph 8.) "Prior to the COVID-19 pandemic, Company-2 imported and distributed hazmat protective suits from a manufacturer in Italy. As COVID-19 spread in the United States, Indvidual-3 used Company-2 to accumulate large quantities of PPE, including facemasks and respirators, and resell them to private brokers and various governmental entities, medical providers, and first responders, often at substantial mark-ups over the prices he paid to acquire the PPE." (Paragraph 9.)

type of mask under consideration, and the applicable EUA or guidance document should be consulted to understand the labeling and other applicable regulatory requirements. Similar analyses apply to gowns, gloves, and face shields.[2]

2) ***Understand the difference between establishment registration and device listing versus permission to market a product in the United States.*** Establishment registration and device listing do not confer permission to market a medical device in the United States. Establishment registration and device listing requirements are part of the FDA's general regulatory controls that device manufacturers typically must follow; they are necessary, but not sufficient, requirements to market a product in the U.S. (Note that certain COVID-19 guidance documents waive the establishment registration and device listing requirements in particular instances; each document should be consulted in order to understand whether and how these requirements have been waived.) Permission to market a medical device is conferred through various approval pathways, such as the 510(k) premarket notification pathway (i.e., "clearance") (or Class I devices exempt from premarket notification), the premarket approval (PMA) pathway, a humanitarian device exemption, an EUA, or compliance with COVID-19 enforcement guidance. These approval, clearance, or authorization pathways are separate and distinct from the establishment registration and device listing requirements.

   Indeed, the FDA's website states as follows: "FDA does not issue Registration Certificates to medical device establishments. FDA does not certify registration and listing information for firms that have registered and listed. Registration and listing does not denote approval or clearance of a firm or their devices." And paragraphs 36-37 of the King Year Printing criminal complaint allege that King Year Printing provided a certification document purporting to state that King Year Printing "was 'registered with the [FDA] pursuant to voluntary cosmetic registration program.'" (Paragraph 36.) The complaint continues to allege that King Year Printing "did not attempt to register with the FDA as a manufacturer of N95 respirators until on or about April 10, 2020, not the March 20, 2020 date this certificate bears. Therefore, this certificate prepared for King Year . . . and disseminated to Individual-1 and others as a marketing tool for U.S. buyers . . . provided a false impression that King Year had registered with the FDA as a foreign manufacturer of N95 masks when it had not." (Paragraph 37.)

3) ***Critically assess any products where the FDA's logo appears on the product packaging.*** The FDA's website states that the "FDA logo is for the official use of the [FDA] and not for use on private sector materials. To the public, such use would send a message that FDA favors or endorses a private sector organization or the organization's activities, products, services, and/or personnel (either overtly or tacitly), which FDA does not and cannot do. Unauthorized use of the FDA logo may violate federal law and subject those responsible to civil and/or criminal liability." And as described in Paragraph 40 of the criminal complaint

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[2] The FDA has periodically revised and updated the applicable guidance documents and EUAs on an almost weekly basis throughout the pandemic, and care must be taken to ensure that the most up-to-date version of a document is being consulted. The FDA's EUA website is available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization, and the FDA's COVID-19 guidance documents are available at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders.

against King Year Printing, the use of the FDA logo (in addition to the NIOSH logo, as well as the CE and GB logos, for the European Union and Chinese regulations) on the labeling of the box packaging was noticeable to U.S. Customs and Border Protection (CBP) law enforcement personnel upon inspection.

4) ***Critically assess the manufacturing quality and testing reports of the product under consideration.*** As alleged in the King Year Printing criminal complaint, a test report that was supplied "purportedly certified that the masks manufactured by King Year met the NIOSH standard for particulate filtration efficiency. The test report was from a non-accredited laboratory and appears to have been false. The report did not include a model number or brand name for the masks tested, rendering it impossible to verify whether the masks allegedly tested were the Subject Respirators sold . . . Additionally, the pictures of the masks depicted in the report were generic and appeared to be different from the Subject Respirators later imported . . . For example, unlike the Subject Respirators, the masks depicted in the . . . report were not stamped with any marks or logos, were not embroidered with 'N95,' and had ear loops that visibly appeared to be made of different material." (Paragraph 38.)

5) ***If importing from a foreign country, understand whether the foreign country from where the product will be exported has placed any restrictions on the export of medical products from the country.*** Some countries, including the United States and China, have placed restrictions on the export of PPE, which may trigger supply chain issues. PPE procured from international vendors that is successfully exported and shipped to the United States will still be subject to U.S. importation and customs requirements. Companies may expect additional scrutiny from both CBP and FDA to ensure compliance, particularly if this is the first time the international vendor or the U.S. company is importing products to the United States; those transactions could be screened as part of routine monitoring.

   There are a number of best practices that help eliminate or mitigate import/export issues related to PPE. First, prior to importing, consider contacting the CBP ports of entry office where your merchandise will enter the United States. If contacting CBP prior to importing, ask to speak with a CBP COVID-19 import specialist. Be prepared with a full and complete description of the imported items and to answer specific questions such as (i) the country of origin of the merchandise and manufacturer, (ii) the composition of the merchandise, (iii) the intended use of the item, and (iv) pricing/payment information (in order to properly determine the value of the shipment). For more information on the classification of merchandise, consult the Harmonized Tariff Schedule (HTS), which contains the actual HTS number and tariff classification guidelines that explain how to properly classify merchandise. Finally, consulting with a licensed customs broker while considering international manufacturing vendors can significantly streamline the U.S. import process and prevent unnecessary issues.

6) ***End users can consider best practices on how to segregate and manage the various sources of PPE.*** As a best practice, hospitals, medical offices, and other health care providers can consider whether and how to segregate cleared products, such as surgical masks and surgical gowns, from non-cleared but otherwise authorized products, such as face masks, that are permitted for use with a medical purpose under the terms of the FDA's guidance documents or EUAs.

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