Kilpatrick

Insights: Alerts

Practical Considerations for Manufacturers Pivoting to PPE Production to Combat COVID-19 Pandemic

March 25, 2020

Written by **Stephanie N. Bedard, Jon Neiditz, Ronald L. Raider, Jason M. Wenker**

Please note: The below information may require updating, including additional clarification, as the COVID-19 pandemic continues to develop. Please monitor our main COVID-19 Task Force page and/or your email for updates.

The COVID-19 pandemic has presented virtually unprecedented health challenges to the United States and the world at large. But the pandemic also may present both civic and business opportunities. One of the most immediate and pressing issues is the shortage of personal protective equipment ("PPE") that protect health workers on the front lines. The Food and Drug Administration ("FDA"), which regulates the manufacture of PPE, has candidly stated that "the need for personal protective equipment (PPE), such as surgical masks, surgical and isolation gowns, and surgical suits, may outpace the supply available to healthcare organization[s] during the Coronavirus Disease 2019 (COVID-19) outbreak." The FDA emphasizes its door is open to collaborate with businesses willing and able to manufacture PPE.

Any business that has interest in entering the medical PPE market should start with a general recognition that the FDA implements a regulatory approval program that is tailored to reflect the relative medical risks and benefits of each PPE and medical device. The approval programs may not be as onerous as anticipated, particularly in these highly unusual COVID-19 times. The FDA is demonstrating flexibility and transparency in seeking to increase supply of these products. This, combined with industry collaborations, will likely reduce typical market entry barriers to enable public interest contributions and product line expansion quickly.

For businesses considering a retrofit to support the manufacture of PPE and other critical supplies, there are some initial considerations to take into account in evaluating whether and how to modify manufacturing capabilities.

The first step in modifying manufacturing facilities for PPE production is to determine which classification of products or components your business may have the capability to produce. Medical devices are classified as Class I, Class II, or Class III based on the risks associated with the use of the device. Class I products have the lowest risk, while Class III products have the highest risk.

Approximately 35% of device types are Class I products. Class I products typically are exempt from pre-market review. Over half – 53% of products – are classified as Class II, which generally present a moderate risk of harm to the user and typically require premarket notification through a 501(k) submission to the FDA. The remaining

9% of products are designated as Class III because they sustain or support life, are implanted, or present a potential high risk of illness or injury. Class III products require FDA review through premarket approval ("PMA") or humanitarian device exemption ("HDE").[1]

Once you determine which classification of PPE fits your business capabilities, the next step in shifting towards PPE production is to determine the specific products, devices, and equipment that align best with your current capabilities. The federal government, and particularly the FDA, has acted quickly in the past few weeks to loosen certain regulatory hurdles and to offer manufacturers with practical guidance for manufacturing certain types of PPE. This step includes consideration of the following types of PPE facing a critical shortage:

- ***Manufacturing surgical masks, gowns, and other related products used by health care professionals interacting with COVID-19 patients or suspected patients:*** On March 11, 2020, the FDA issued a FAQ designed to assist manufacturers in facilitating the production of masks and gowns under the following product codes: surgical masks (FXX); surgical masks with antimicrobial/antiviral agent (OUK); pediatric/child facemasks (OXZ); surgical gowns (FYA); isolation gowns and surgical apparel accessories (FYC, LYU, OEA); and surgical suits (FXO). The FAQ also describes the best method for manufacturers to contact the FDA and describe their proposed manufacturing approach, including proposals for expedited reviews of premarket submissions and of manufacturing site changes for Class III device manufacturers.

  For example, a consortium of companies, including HanesBrands and Parkdale Mills America, have contracted with the federal government to begin manufacturing FDA-approved masks. HanesBrands and the other consortium participants have indicated that they are working with Fruit of the Loom, SanMar, Beverly Knits, the National Council of Textile Organizations, and other apparel companies to share product specifications and patterns for the FDA-approved masks. If manufacturers in the textile supply chain are interested in dedicating resources to the consortium, they are encouraged to reach out to the National Council of Textile Organizations.

- ***Manufacturing vital sign-measuring devices:*** On March 20, 2020, the FDA issued new guidance and a related news release permitting pre-existing manufacturers of certain FDA-cleared, non-invasive, vital sign and remote patient monitoring devices to expand their use so that health care providers can use them to monitor patients remotely. The devices include those that measure body temperature, respiratory rate, heart rate, and blood pressure.

- ***Manufacturing ventilators and related medical devices:*** On March 22, 2020, the FDA issued guidance and a related news release encouraging both domestic and foreign manufacturers of ventilators and related products to contact the FDA about pursuing an Emergency Use Authorization ("EUA") in order to facilitate the distribution of ventilators and other medical devices in the United States. This includes U.S.-based manufacturers who were previously engaged in making medical devices and who have capabilities to increase supply of these products.

- ***Manufacturing alcohol-based hand sanitizer:*** On March 14, 2020 and March 19, 2020, the FDA issued two guidance documents to communicate its policy for the temporary manufacture of alcohol-based hand

sanitizer products. The first guidance, titled Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency, addresses the temporary compounding of certain alcohol-based hand sanitizers by pharmacists in state-licensed pharmacies or federal facilities and registered outsourcing facilities. The second guidance, Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19), states that the FDA does not intend to take action against manufacturers that prepare alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs. On March 24, 2020 the FDA issued an additional guidance, titled Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19), to further guide manufacturers interesting in assisting with the production of alcohol-based hand sanitizers.

- ***Manufacturing diagnostic testing equipment:*** On March 16, 2020, the FDA updated its policy and issued a news release describing regulatory changes designed to expedite manufacturing capabilities and the availability of diagnostic testing equipment. The FDA has indicated that it does not intend to object to commercial manufacturers distributing and labs using new commercially developed tests prior to the FDA granting an EUA. The FDA has set up a toll-free line, 1-888-INFO-FDA, to help labs and commercial manufacturers with any questions they may have about the EUA process and FDA's policies.

- ***Importation of Personal Protective Equipment:*** On March 24, 2020, the FDA provided instructions to manufacturers regarding the importation of PPE into the U.S. These instructions clarify the types of PPE that can be imported without engaging with the FDA. For questions or concerns about the importation of PPE, the FDA has established a special email inbox, COVID19FDAIMPORTINQUIRIES@fda.hhs.gov, for industry representatives to use as a resource.

In considering the types of PPE and other medical devices in short supply, we encourage you to think about the components that go into those devices and whether you or your supply chain could support the production of needed components for devices to support health care workers and patients.

Our COVID-19 Taskforce stands ready to help you and your business become a part of the fight against the pandemic. We can work with you to contact the FDA, CDC, and other regulatory agencies and help you navigate the regulatory process to position your business to effectively use its resources in this time of need.

If you are interested in discussing a specific area of interest for your business, we recommend that you reach out to your primary Kilpatrick Townsend point of contact. General questions may also be submitted via email to: #COVID-19KTSTaskForce@kilpatricktownsend.com.

Footnotes

[1] https://www.fda.gov/medical-devices/resources-you-medical-devices/consumers-medical-devices.

Related People

Stephanie N. Bedard

t 404.815.6039

sbedard@ktslaw.com

Jon Neiditz

t 404.815.6004

jneiditz@ktslaw.com

Ronald L. Raider

t 404.532.6909

rraider@ktslaw.com

Jason M. Wenker

t 336.607.7416

jwenker@ktslaw.com