In the Midst of the COVID-19 Pandemic, FDA Issues Much Needed Guidance on the Distribution of Face Masks and Respirators

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The novel Coronavirus (COVID-19) has presented many challenges to our healthcare industry, including a shortage of personal protective equipment (PPE). Over the last couple of weeks, we have seen an increased in the number of efforts to provide PPE to our doctors and nurses on the frontline of this crisis, from fashion designers pledging to make masks over Instagram to efforts on Facebook to make face masks to be donated to local hospitals without much guidance from the Food and Drug Administration.[1] With the mounting pressure to increase the availability of face masks for health care providers and consumers, FDA released a new guidance document on Wednesday, March 25, 2020. The guidance document entitled, "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency," is intended "to help address the urgent public health concerns by clarifying the regulatory landscape of face masks and respirators, helping to expand the availability of general use face masks for the general public, and of filtering facepiece respirators (including N95 respirators) for use by health care professionals in healthcare settings."[2]

In the guidance, FDA outlines a risk-based approach to the distribution of masks and respirators, including these products' indications and claims. Generally, face masks fall within the definition of a "medical device" when they are intended for a medical purpose, including for use by health care professionals. Face masks that are not intended for a medical purpose are not medical devices. FDA defines "intended for a medical purpose" to mean that the device "is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease . . . "

It is important to note that, in the guidance, FDA recognized that, "when alternatives, such as FDA-cleared masks or respirators, are unavailable, individuals, including healthcare professionals, might improvise PPE." As such, "FDA does not intend to object to individuals' distribution and use of **improvised PPE when no alternatives**, such as FDA-cleared masks or respirators, are available." (Emphasis added.)

Below are some highlights from the guidance document that may be of interest to those seeking to market and distribute face masks during the pandemic.

- **Face Masks and N95 Respirators Not Intended for a Medical Purpose**
  - Face masks and filtering facepiece respirators marketed to the public for general, non-medical purposes (e.g., construction and other industrial applications) do **not** require a medical device marketing authorization (i.e., 510(k)) and all the other requirements of the Food, Drug, and Cosmetic Act (FD&C Act) do **not** apply to these products, because "they are not intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease."

1 See New York Times article entitled "Christian Siriano and Dov Charney are Making Masks and Medical Supplies Now, available at https://www.nytimes.com/2020/03/21/style/coronavirus-masks-dov-charney-christian-siriano.html.
2 The guidance document is available at https://www.fda.gov/media/136449/download.

- Face masks and respirators are devices when they are intended for a medical purpose, such as prevention of infectious disease transmission (including related uses to COVID-19). They would not be regulated as devices when they are intended for a non-medical purpose, such as for use in construction.
- FDA will look at the following factors to determine if a product is intended for a medical purpose:
  - Whether it is labeled or otherwise intended for use by a health care professional;
  - Whether it is labeled or otherwise intended for use in a health care facility or environment; and
  - Whether it includes any drugs, biologics, or anti-microbial/anti-viral agents.

- **Face Masks Intended for a Medical Purpose that are NOT Intended to provide Liquid Barrier Protection**
  - Generally, FDA recommends that health care providers follow current Centers for Disease Control and Prevention (CDC) guidance regarding PPE that should be used during the COVID-10 outbreak.
  - However, to "ensure the availability of equipment that might offer some benefit to health care providers and the general public during the COVID-19 outbreak. . . FDA does not intend to object to the distribution and use of face masks (not including respirators) that are intended for medical purpose (whether used by medical personnel or the general public), without compliance with the following regulatory requirements "**where the face masks does not create an undue risk in light of the public health emergency**: prior submission of a premarket notification 510(k), Registration and Listing requirements, Quality System Regulation requirements, reports or corrections and removals, Unique Device Identification requirements." (Emphasis added.)
  - FDA currently believes such devices would not create an undue risk where:
    - The product includes labeling that accurately describes the product as a face mask (as opposed to a surgical mask or Filtering Facepiece Respirator) and includes a list of the body contacting materials (which does not include any drugs or biologics);
    - The product includes labeling that makes recommendations that would reduce sufficiently the risk of use, for example, recommendations against: use in any surgical setting or where significant exposure to liquid, bodily, or other hazardous fluids may be expected; use in a clinical setting where the infection risk level through inhalation exposure is high; and use in the presence of a high intensity heat source or flammable gas; and
    - The product is not intended for any use that would create an undue risk, for example, the labeling does not include uses for antimicrobial or antiviral production or related uses or uses for infection prevention or reduction or related uses and does not include particular filtration claims.

- **Surgical Masks Intended to Provide Liquid Barrier Protection**
  - Surgical masks are class II devices that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials and are tested for flammability and biocompatibility.
  - FDA does not intend to object where . . . . surgical masks are distributed and used without prior submission of a 510(k) premarket notification and the surgical masks do not create an undue risk in light of the public health emergency. The agency currently believes such devices would not create an undue risk where:
    - The product meets fluid resistance testing (liquid barrier performance);
    - The product meets class I or Class II flammability requirements . . . (unless labeled with a recommendation against use in the presence of high intensity source or flammable gas);
    - The product includes labeling that accurately describes the product as a surgical masks and includes a list of boy contacting materials (which does not include any drug or biologics);
    - The product is not intended for any use that would create an undue risk, for example, the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses for infection prevention or related uses, and does not include particulate filtration claims.

While FDA is allowing for the marketing and distribution of face masks and respirators without the requirement of a 510(k) submission, as long as the above conditions are met, the guidance document also outlines the FDA's intended approach for Emergency Use Authorizations (EUAs) for Masks and Respirators with the intend of increasing the number of FDA-cleared devices on the market. The agency welcomes the opportunity to work with manufacturers not previously engaged in medical device device as well as foreign manufacturers who whose products are not currently marketed in the U.S.

AGG Observations

- Individuals interested in making and distributing general use face masks should be aware that these products cannot be distributed for a medical purpose (i.e., protection from COVID-19). That also means that they cannot be labeled or intended to be use by a health care professional or in a health care facility or environment.
- A product distributed for the purpose of protecting a consumer or heath care provider from exposure to COVID-19 is a medical device, subject to FDA regulation.
- FDA is not objecting to an individual's distribution and use of "improvised PPE" when there are no alternatives available, such as FDA-cleared masks and respirators. While there is a shortage of PPE in our country, the guidance does not provide any help as to what it considers to be an "improvised PPE."
- FDA is still encouraging manufacturers to seek out EUAs for facemasks and respirators as FDA-cleared products provide the best defense against exposure to COVID-19
- FDA is working overtime to get these products reviewed and available to health care providers and consumers as evidenced by the late evening release of this guidance document.
- While FDA is exercising enforcement discretion over these products, when specific conditions are met, companies should still be aware of the potential for personal injury claims that could arise from a consumer's reliance on their products after this pandemic is over.

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