How is the 2019 Novel Coronavirus (COVID-19) pandemic continuing to impact food, drugs, and medical devices?

As the 2019 Novel Coronavirus (COVID-19) outbreak persists, the FDA is continuing to take action and provide guidance on a regular basis. To help attorneys, providers, and other stakeholders monitor the dynamic nature of the government’s virus response, this Strategic Perspective compiles FDA information on testing, supply chains, consumer protection, and risk mitigation (for information about earlier FDA and CDC efforts related to the COVID-19 pandemic, see The FDA and CDC response to COVID-19, March 26, 2020).

Guidance

The FDA is issuing guidance at a rapid rate to address the COVID-19 public health emergency. The guidance is being implemented without the usual prior public comment because the FDA determined that prior public participation for the guidance was not feasible or appropriate. On March 27, 2020, the FDA announced its intention to periodically publish a consolidated Notice of Availability of COVID-19 guidance documents rather than a separate notice for each guidance document. These COVID-19 related guidance documents can be found on the agency’s dedicated page.

Treatments

On May 11, 2020, the agency issued the guidance on pre-investigational new drug application (pre-IND) meeting requests, drug development, and diagnostic tests, in the hope of helping industries react to and help in the effort against COVID-19. Other guidance was issued on May 8, 2020, on postmarketing adverse event reporting for medical products, and on compounding certain drugs for hospitalized patients by outsourcing facilities or by pharmacy compounders not registered as outsourcing facilities (see COVID-19 guidance documents issued on testing, products for treatment, and drugs, May 12, 2020).

Testing

On May 15, 2020, the FDA issued a final guidance on the agency’s policy for coronavirus tests. The guidance includes four policies that will help facilitate the development and use of SARS-CoV-2 tests. Two policies center around emergency use authorization (EUA) submission to the FDA or bypassing the EUA when the test is developed under the state’s authority; one policy relating to commercial manufacturers rapid distribution of diagnostics for specimen testing while EUA is being prepared; and a policy regarding the use of serological testing (see FDA issues guidance on development of coronavirus tests, May 15, 2020).

Supply Chain

As the pandemic drags on, the supply chains for drugs, personal protective equipment (PPE), and other medical devices, continue to be a focus for the FDA.

Facemasks. On March 27, 2020, in an effort to address shortages amid the COVID-19 public health crisis, the FDA issued a guidance easing the restrictions on face masks and respirators for use by the general public and health care professionals. According to the guidance, the FDA will not object to the distribution and use of face masks that are intended for a medical purpose without full regulatory compliance provided the face mask does not create an undue risk (see FDA eases restrictions on face masks and respirators amid COVID-19 crisis, March 27, 2020).
On April 14, 2020, HHS issued an interim final rule to update regulatory requirements used by the CDC’s National Institute for Occupational Safety and Health (NIOSH) (see HHS cites COVID-19 as good cause for circumventing APA rules, approves new respiratory protection, April 14, 2020). Effective immediately, HHS’s final interim rule provides for approval of and standards for a new class of powered air-purifying particulate respirator (PAPR), known as the PAPR100, which may be better suited for health care workers and other first responders compared to other PAPRs.

On April 11, 2020, the FDA authorized the emergency use of Advanced Sterilization Products, Inc. (ASP) STERRAD Sterilization Systems for the use of decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms during the COVID-19 pandemic. The agency found reasonable belief that use of the systems may be effective in preventing exposure to pathogenic airborne particulates when there are insufficient supplies of N95 respirators during the pandemic by decontaminating N95 respirators for single-user reuse.

**Gowns.** The FDA has also issued guidance on its enforcement policy for gowns, other apparel, and gloves during the COVID-19 public health emergency (see FDA policy to expand availability of gowns, gloves, and other apparel, April 1, 2020). According to the FDA, the guidance provides a policy to help expand the availability of surgical apparel for health care professionals and surgeon’s and patient examination gloves. The guidance outlines the FDA-regulated and non-regulated gowns, other apparel, and gloves, and the FDA’s relaxation of regulatory enforcement.

**Hoarding.** HHS published a notice, on March 30, 2020, designating health and medical resources necessary to respond to the COVID-19 crisis that are scarce or the supply of which would be threatened by excessive accumulation. The Notice comes in response to a Trump Administration executive order to prevent the hoarding of health and medical resources necessary to respond to the spread of COVID-19 within the U.S. The materials included filtering facepiece respirators, portable ventilators, and drug products with the active ingredient chloroquine phosphate or hydroxychloroquine HCl.

**Drugs.** On April 1, 2020, the FDA issued guidance to assist applicants and manufacturers in providing FDA notifications about changes in the production of certain drugs and biological products. The guidance outlines who should notify the FDA, when and how those notifications should be submitted, and what details to include in notifications that will ensure the FDA has information it needs to help prevent or mitigate shortages (see Manufacturers get information on notifying FDA about interruptions during COVID-19 emergency, April 1, 2020).

**CARES Act.** The Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which was signed into law on March 27, 2020, took steps to alleviate drug supply chain shortages. Under the CARES Act, the review of drug applications to help with shortages of emergency drugs will be prioritized. At the same time, drug manufacturers have new requirements about reporting a discontinuation and disruption of access to active pharmaceutical ingredients. Manufacturers of certain drugs and medical devices critical to public health during a public emergency must create, maintain, and implement risk management plans related to shortages. Also, those manufacturers will be subject to shortage-related inspections by HHS (see Coronavirus Aid, Relief, and Economic Security Act (CARES Act) impacts health industry, health law, March 30, 2020).

**Food.** For the duration of the COVID-19 pandemic, the FDA has suspended onsite inspection audits for food imported into the U.S. In the meantime, the importer or receiving facility is required to verify safety in alternate ways (see FDA temporarily suspends onsite food audits in coronavirus-affected countries, March 26, 2020).

**Warning Letters**

On April 10, 2020, the FDA and Federal Trade Commission (FTC), issued warning letters to numerous companies selling unapproved COVID-19 products with false or misleading claims during the pandemic. There are currently no FDA-approved products to prevent or treat COVID-19. Both agencies noted that consumers concerned about COVID-19 should consult with their health care provider.

Additionally, in a May 7, 2020 press release, the FTC announced that it had sent 45 warning letters to marketers making unsubstantiated claims about products for the prevention or treatment of COVID-19. The FTC had
previously sent almost 100 letters to companies and individuals as part of its campaign. These include letters to sellers of vitamins, herbs, colloidal silver, teas, essential oils and other products represented to be "proven" as coronavirus treatments or preventatives.

**Conclusion**

As the COVID-19 outbreak continues to impact daily life, the FDA will continue to provide guidance and take action to address the spread of the virus. Stakeholders should monitor the FDA's [Coronavirus Disease 2019](https://www.fda.gov) webpage and the CDC's [Coronavirus (COVID-19)](https://www.cdc.gov) information page for the latest agency action.