
Health Law Daily Wrap Up

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How is the COVID-19 outbreak impacting FDA action, CDC guidance, and food, drug, and medical device supply chains?

As the novel coronavirus disease 2019 (COVID-19) outbreak continues to develop, the FDA and the Centers for Disease Control and Prevention (CDC) are taking action and providing guidance on a daily basis. To help attorneys, providers, and other stakeholders monitor the dynamic nature of the government’s virus response, this Strategic Perspective compiles recent CDC and FDA information on testing, supply chains, consumer protection, and risk mitigation.

Availability and regulation of COVID-19 testing

On March 6, 2020, the FDA announced it would allow certain laboratories to use in vitro diagnostics which were developed and validated without FDA emergency use authorization in order to ensure the wide availability of testing for COVID-19 (see FDA authorizes emergency coronavirus testing, issues guidance for labs amid outbreak, March 6, 2020). Previously, on January 28, 2020, the FDA announced that it was actively leveraging its expertise and had begun employing the full range of public health authorities to facilitate the development and availability of investigational medical products to help address the urgent public health situation (see FDA assisting in efforts to combat Coronavirus, January 28, 2020).

The FDA also announced, on March 13, 2020, that it is not objecting to the New York State Department of Health (NYSDOH) authorizing certain laboratories in New York to begin patient testing. This means that NYSDOH authorized labs will not need an additional approval from the FDA prior to engaging in patient testing. Additionally, the FDA authorized the Roche cobas SARS-CoV-2 Test, the third Emergency Use Authorization (EUA) granted for a diagnostic test during the COVID-19 outbreak.

On March 13, 2020, the FDA issued the fourth COVID-19 diagnostic Emergency Use Authorization (EUA) to Thermo Fisher for its TaqPath COVID-19 Combo Kit. The TaqPath COVID-19 Combo Kit is the second commercially distributed test to receive an EUA during the COVID-19 outbreak.

On March 16, 2020, the FDA issued two additional EAUs to: Hologic for its Panther Fusion SARS-COV-2 Assay, and Laboratory Corporation of America (LabCorp) for its COVID-19 RT-PCR test.

On March 21, 2020, the FDA issued an EAU for a point-of-care COVID-19 diagnostic for the Cepheid Xpert Xpress SARS-CoV-2 test. The test will allow results to be available within hours, rather than days, like existing tests.

What is the impact on the food, drug, and device supply chain?

The FDA has issued surgical mask and gown conservation strategies, in recognition of the fact that the need for personal protective equipment (PPE) may outpace the supply as a result of the COVID-19 outbreak.

Inspections. On March 10, 2020, the FDA announced that it would postpone most of its inspections outside of the U.S. through April. In response to the COVID-19 outbreak. The decision was based in part upon State Department Level 4 travel advisories in which travel is prohibited for U.S. government employees. The agency also decided to halt inspections due to CDC travel recommendations, travel restrictions imposed by other countries, and the FDA’s belief that it can conduct oversight using other methods.
Subsequently, on March 18, the FDA announced that it would also scale back domestic inspections. The FDA noted that it would temporarily postpone domestic inspections to protect the health of staff and contractors and to allay industry concerns regarding visitors.

**Status update.** The FDA released a supply chain update on February 27, 2020 detailing the status of drug, medical device, biologic, food, and animal drug supply chains. The FDA has not, to date, issued a more recent announcement of this kind.

**Drugs.** In its announcement, the FDA indicated that it was aware of a shortage of a human drug caused by a shortage of an active pharmaceutical ingredient, manufactured at a site impacted by COVID-19. The FDA indicated that it was working the manufacturers to mitigate the shortage. The FDA did not indicate which human drug was at issue. The FDA also indicated that it was in contact with more than 180 manufacturers of human drugs so that the agency could anticipate and mitigate any additional supply disruptions. As part of this, the FDA identified 20 drugs, which solely source their active pharmaceutical ingredients or finished drug products from China. The FDA indicated that these are non-critical drugs and currently face no shortages.

**Medical devices.** The FDA announced, in the February 27 update, there are 63 manufacturers which represent 72 facilities in China that produce essential medical devices. The agency indicated that it was in contact with all of them and despite adverse effects (including the quarantine of workers) there are currently no shortages reported. Additionally, despite reports of increased market demand for personal protective equipment—surgical gowns, gloves, masks, respirator protective devices, or other medical equipment designed to protect the wearer from injury or the spread of infection or illness—the FDA indicated no reports of specific widespread shortages. However, the FDA acknowledged reports of increased ordering as facilities prepare for the outbreak. Subsequent to the February update, the FDA has taken several steps to address shortages of medical supplies. On March 20, 2020, the FDA issued a policy allowing manufacturers of certain FDA-cleared non-invasive, vital sign-measuring devices to expand their use so that health care providers can use them to monitor patients remotely.

**Respirators.** On March 2, 2020, the FDA issued an EUA to make more respirators, including certain N95s, available to health care personnel. The EAU made it possible for respirators currently indicated for use only in industrial settings to be used in a health care setting by health care personnel during the COVID-19 outbreak. On March 21, 2020, the FDA announced a policy to expand the availability of ventilators as well as other respiratory devices and their accessories during this pandemic. Under the new policy, the FDA does not intend to object to limited modifications to the indications, claims, functionality, or to the hardware, software, or materials of FDA-cleared devices used to support patients with respiratory failure or respiratory insufficiency, without prior submission of a premarket notification.

**Facemasks.** The CDC has issued a series of "strategies or options to optimize supplies of facemasks in healthcare settings when there is limited supply." The strategies include canceling elective procedures requiring the use of facemasks, removing facemasks typically provided to visitors, and implementing extended use policies for reuse of the same facemask. Additionally, on March 18, 2020, the Trump Administration invoked a 70-year old law, the Defense Production Act, to direct the production of private companies to mitigate shortages in masks, ventilators and other medical supplies. On March 24, 2020, the FDA issued instructions to manufacturers on importing personal protective equipment (PPE) and other devices. The instructions clarify the types of PPE that can be imported without FDA engagement. In order to avoid supply disruptions, the FDA indicated it is engaging in "maximum flexibility" regarding the importation of PPE.

**Hand sanitizer.** On March 20, 2020, the FDA published guidance establishing the agency’s position that, in order to address "significant supply disruptions" of hand sanitizers, it would not take action against manufacturing firms that prepare alcohol-based hand sanitizers for consumer use and for use as health care personnel hand
rubs. Under the new policy, the FDA will allow manufacturers to prepare alcohol-based hand sanitizers even if they are not currently regulated by FDA as drug manufacturers.

The FDA also issued guidance on March 20 announcing it would not take action against compounders that prepare alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs. The FDA will allow compounders to produce hand sanitizer as long as they do not add other active or inactive ingredients.

**Blood.** On March 19, 2020, the FDA announced that blood donations have been dramatically reduced as a result of the COVID-19 outbreak. The FDA called on donors to donate blood and made recommendations about how to do so safely.

**Biologics, food, animal drugs.** In the February 27, 2020 update, the FDA noted no shortages of biologics, food, or animal drugs. On March 24, 2020, the FDA announced that there are currently no nationwide shortages of food, despite localized reports of shortages.

However, on March 18, 2020 due to unprecedented demand on grocery stores, the FDA issued a temporary policy for FDA Food Safety Modernization Act (FSMA) supplier verification onsite audit requirements. Under the temporary policy, the FDA will temporarily not enforce FSMA supplier verification onsite audit requirements if other appropriate supplier verification methods are used instead. Examples of "other verification methods" include sampling and testing or a review of food safety records.

**Shortages.** Although reported shortages, as of February 27, 2020, were minimal, the FDA cautioned that federal law does not impose an obligation on manufacturers to report on circumstances which might interrupt the supply chain. Additionally, federal law does not require manufacturers to respond to the FDA’s questions regarding potential supply chain disruptions.

**FDA guidance for drugs and devices during COVID-19 pandemic**

On March 18, 2020, the FDA issued guidance to assist medical device clinical trial sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP), and minimizing risks to trial integrity during the COVID-19 pandemic. The guidance acknowledges that previously established clinical trial protocols may need to be modified to address COVID-19.

On March 19, 2020, the FDA responded to news reports stating the use of non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, could worsen coronavirus disease. The agency announced it is not aware of scientific evidence connecting the use of NSAIDs, like ibuprofen, with worsening COVID-19 symptoms.

On March 22, the FDA issued guidance related to risk evaluation and mitigation strategies (REMS) requirements for laboratory testing of certain drugs. Under the new policy, to alleviate burdens related to COVID-19, although REMS requirements will remain in effect, the FDA will not enforce the REMS requirements.

**Consumer protection action by the FTC and FDA**

The FTC and FDA announced on March 10, 2020, that they issued seven warning letters regarding the marketing of unapproved products intended to prevent or treat novel coronavirus disease 2019. According to the FDA, there are no approved vaccines, drugs, or investigational products currently available to treat or prevent the virus (see Federal agencies watching for antitrust, consumer protection violations stemming from COVID-19 crisis, March 10, 2020).

On March 20, 2020, the FDA issued a reminder to consumers that the FDA has not authorized any test that is available to purchase for testing yourself at home for COVID-19. The agency cautioned consumers to be aware of fraudulent health claims, tests, and products related to COVID-19.

**Contamination.** On February 25, 2020, the FDA announced: "currently, we are not seeing the impacts of this outbreak resulting in an increased public health risk for American consumers from imported products. There is no evidence to support transmission of COVID-19 associated with imported foods and there have not been any cases of COVID-19 in the United States associated with imported goods."
Infectious disease guidance from the CDC

The CDC has issued a wide variety of information and guidance on the nature of the virus and mitigation strategies.

On March 15, 2020, the CDC recommended that for the following 8 weeks, organizers (whether groups or individuals) cancel or postpone in-person events that consist of 50 people or more throughout the United States. The CDC noted that the "recommendation is made in an attempt to reduce introduction of the virus into new communities and to slow the spread of infection in communities already affected by the virus."

Following the CDC's updated guidance, several states have taken still greater action to reduce the spread of the virus. New York, Illinois, Connecticut, California, and Pennsylvania have shut down most business and asked restaurants and bars to take strict measures, including prohibiting guests, with the exception of take-out and delivery.

What's next for COVID-19?

As the COVID-19 outbreak continues to impact daily life, the CDC and 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 webpage and the CDC's Coronavirus (COVID-19) information page for the latest agency action.