FDA Updates Prevention, Diagnosis, and Treatment Policies in Response to COVID-19

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To limit the spread of COVID-19 throughout the United States, the Food and Drug Administration (FDA) has promulgated policies to focus on the prevention, diagnosis, and treatment of the COVID-19 virus. Further, as states implement COVID-19 control measures, some day-to-day enforcement regulations have been relaxed. FDA polices in response to the pandemic and control measures affecting healthcare providers and products liability are summarized below.

Update on Diagnostic Tests and Treatments for COVID-19

- Diagnostic Tests – The rapid increase of presumptive COVID-19 cases combined with the lack of COVID-19 diagnostic tests forced the FDA to allow medical device makers to distribute unapproved FDA diagnostic tests. This is an unprecedented move, as the announcement also circumvents the FDA's own expedited Emergency Use Authorization (EUA) for diagnostic tests, and gives a blanket authorization for use of any test–free from liability–to confirm COVID-19 cases. For more information refer to this article.
- Treatment – The bulk of FDA's resources are pooled to find a viable prevention or treatment option for COVID-19. While the FDA has not approved any drugs or vaccines to prevent or treat the virus, the agency is planning and preparing for large scale production of a drug, as well as identifying possible supply chain issues in distributions. Moreover, the FDA has expanded clinical trials of various investigational drugs under EUA, in hopes to prevent the spread of COVID-19. For a complete update, including drugs undergoing EUA clinical trials, refer to this press release by the FDA.

Policies affecting Healthcare Providers

- Remote Monitoring Devices for Telemedicine – For the purpose of reducing human interactions, the FDA has expanded the use of non-invasive remote monitoring devices for the duration of the pandemic. Monitoring devices, such as those that measure oxygen saturation, respiratory rate, and body temperature can be transmitted to a physician through Bluetooth, Wifi, or mobile app, via hardware and software modifications. These new modifications do not need FDA approval, but the cybersecurity controls should be maintained and developed. More information on maintaining legally-compliant cybersecurity practices in the time of COVID-19 can be found here, while more information regarding the types of monitoring devices can be found here.
- Facemasks – On March 18, 2020 the U.S. Senate passed legislation that would extend products liability protection to N95 facemasks approved by the National Institute for Occupational Safety and Health (NIOSH) to be used in clinical settings. Before this legislation was passed, only N95 masks approved by the FDA were given this product liability protection. Now, N95 masks approved by

NIOSH, typically used for construction and other industrial purposes, can be used in hospitals to protect healthcare workers from contracting COVID-19. The FDA has extended this protection to Surgical Masks and Filtering Facepiece Respirators, as well. Additionally, the FDA is currently working with manufacturers to facilitate a method for the safe reuse of facemasks. The complete list of facemasks free from liability and the reporting of safe reuse procedures for facemasks can be found here.

- Hand Sanitizer – Because of the shortage of hand sanitizer, the FDA has relaxed the regulations for the manufacturing of hand sanitizer, by allowing hand sanitizer manufacturing to be conducted by firms that have not been previously approved for consumer use and without the supervision by a licensed pharmacist. Further, the FDA has provided a procedure for preparation for any entity or consumer alleviating the demand for hand sanitizer. More information, as well as the hand sanitizer preparation procedure can be found here.

Policies affecting Clinical Trials and Drug Reporting

- Clinical Trials protocols impacted by COVID-19 Control Measures – With an eye towards safety and disease prevention, the FDA has issued a nonbinding guidance policy to assess the continuation of drug studies for ongoing clinical trials. Entities conducting studies impacted by COVID-19 control measures have the discretion to determine whether to continue the clinical trial or alter procedures to reduce human-to-human contact. Any changes to clinical testing and procedures should be made with consultation of IRB investigators, but can be altered without IRB approval to reduce human interaction. Drug studies impacted are required to disclose alternative procedures used, impact of alternative procedures, and a list of participants affected in the clinical study report. Factors to determine whether to continue clinical trials, suggestions for alternative procedures, and the full FDA guidance can be found here, while guidance for control measures for employers can be found here.
- Clinical Trials Regarding REMS - The FDA has also promulgate similar, nonbinding guidelines for drugs with Risk Evaluation and Mitigation Strategy (REMS). For these limited cases where drug efficacy must be tested periodically in a laboratory or drug delivery is required to be conducted in a clinical setting, health care providers must use their medical judgement to determine whether to continue administering drug to participants against the risk of spreading COVID-19. Moreover, the providers must communicate their reasoning behind their judgment to the participants, including both the risks and benefits. The full FDA guidance on REMS drug studies can be found here.
- Adverse Reporting During a Pandemic – The FDA has permitted the delay in reporting of adverse events of medical products and dietary supplements due to the inability to produce such reports caused by employee absenteeism during COVID-19 control measures. This delay is permitted a good faith effort in reporting adverse events in their diminished capacity, notifies the agency of the impending delay, and reports any adverse events to the agency at the end of the pandemic. The full guidance for delaying adverse reporting during a pandemic can he foundhere. To prepare for delays during the pandemic and in the future, firms should create or update their a continuity of operations plan (COOP) to ensure continued daily business operations during pandemics and other potential events that pose a risk to business continuity. Resources for developing a COOP can be found here.