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CLIENT ALERT

FDA Relaxes Certain Lab and Imaging Test Requirements for REMS Programs During the COVID-19 Pandemic

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On March 22, 2020, the Food and Drug Administration (FDA) issued a press release announcing that, in light of the emergent circumstances of the COVID-19 pandemic, it was issuing a Guidance for Industry and Health Care Professionals on an immediate basis to provide sponsors and healthcare providers with more flexibility in complying with certain Risk Evaluation and Mitigation Strategy ("REMS") program obligations during the public health emergency declared by the Secretary of the Department of Health and Human Services (HHS) on January 31, 2020. *See* Policy for Certain REMS Requirements During the COVID19 Public Health Emergency Guidance for Industry and Health Care Professionals (March 2020) ("the Guidance").

Specifically, the FDA's Principal Deputy Commissioner, Amy Abernethy, M.D., Ph.D., was quoted as stating...

> **"The FDA recognizes that during the COVID-19 public health emergency, the completion of some REMS-required laboratory testing or imaging studies may be difficult because patients suspected of having COVID-19 may be self-isolating and/or subject to quarantine. Under these circumstances, undergoing testing or imaging studies in order to obtain a drug that is subject to a REMS can put patients and others at risk for transmission of the coronavirus. We will continue to work with sponsors to ensure that patients have appropriate access to the medications they need."**

The FDA is specifically addressing the practical complications of referring patients for laboratory tests and imaging studies as part of the ongoing process of gathering relevant clinical data for the REMS assessment and patient treatment process. For example, for many drugs subject to a REMS, patients may not be prescribed certain drugs without a healthcare professional first ordering and reviewing the results of laboratory or imaging tests. These REMS requirements are referred to as "elements to assure safe use." Concerns have been raised that the process of prescribing and performing these tests may potentially expose patients (who may already be vulnerable to infection), physicians, other providers, and provider employees to the Coronavirus.

Accordingly, the FDA's new, temporary guidance is that for drugs that are currently subject to a REMS that incorporate laboratory testing or imaging requirements, providers who are making the prescribing and/or dispensing decisions about whether these tests should be performed will be afforded some latitude to exercise their medical judgment as to whether there is a "compelling" reason not to order the test or study for the patient during the current public health emergency. Health care providers should also "use their best medical judgment in weighing

the benefits and risks of continuing treatment in the absence of laboratory testing and imaging studies. Health care providers should also communicate with their patients regarding these judgments, including the risks associated with it."

In light of this Guidance, the "FDA does not intend to take action against sponsors and others for the duration of the public health emergency for failing to adhere to REMS requirements for certain laboratory testing or imaging studies." Enforcement forbearance by the FDA under sections 505-1(f)(3)(d) or (e) of the FD&C Act (21 U.S.C. § 355-1 (f)(3)(d) or (e)) during the public health emergency declared by the Secretary of HHS on January 31, 2020, will apply, provided that such accommodations regarding laboratory and imaging testing were made based on the judgment of a health care professional. The FDA mandates that manufacturers should take steps to document and summarize in their next REMS Assessment Report the steps that were taken to accommodate patient access to these REMS drugs during this COVID-19 public health emergency.

This temporary Guidance will be in effect for the duration of the currently declared public health emergency, which may be ended either by a declaration from the Secretary of HHS or, if not otherwise extended by the Secretary, upon the expiration of the 90-day period beginning on the date the Secretary declared the existence of the public health emergency, whichever occurs first.

FDA guidance documents reflect the FDA's current thinking on a subject and are not requirements but, rather, recommendations. While this Guidance was issued without a prior comment period, the FDA will be accepting public comments on the Guidance going forward. This guidance reflects the FDA's attempt to address a thorny set of considerations for the treatment of patients undergoing therapy with a drug subject to a REMS, but it by no means provides the answers to all important considerations that will come into play. For example, how should the accommodations be documented in the REMS report?

For further information or questions on requirements for REMS programs during the COVID-19 pandemic, please contact T. Reed Stephens or your Winston relationship attorney.

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