WINSTON & STRAWN LLP

IN THE MEDIA

Why Emergency Authorization of COVID-19 Therapies Could Pose Regulatory Questions

MARCH 11, 2021

Winston & Strawn Partner Reed Stephens shares his insights on how the Biden administration may handle vaccine development and emergency use authorizations after the COVID-19 public health emergency recedes.

Few of the COVID-19 therapies in use in the U.S. have won full FDA approval. The widespread use of emergency use authorization may accelerate the distribution of disease-modifying agents and vaccines to patients, but it also could cause regulatory complications.

One factor influencing the U.S. regulatory landscape at large is “the fact that the original declaration of a public health emergency by the prior Secretary of Health and Human Services in the past administration is still in place,” said Reed Stephens. “Many long-established regulatory and statutory obligations have been put on pause in response to the ongoing public health emergency.”

But the Biden administration is charting a new course in terms of pandemic response, swiftly invoking the Defense Production Act to facilitate vaccine production, for instance. “Once the public health emergency declaration lapses, we are likely to see the new administration’s FDA and HHS leaders, with active oversight from Congress, take a thoughtful approach to pandemic response planning that looks closely at the framework of a proactive vaccine research and development program under a private-public partnership that will inspire public confidence and is not saddled with the label of ‘emergency’ response,” Reed said.

Read the full article here.

1 Min Read

Related Locations

Washington, DC

Related Topics

COVID-19

Related Regions

North America

Related Professionals

T. Reed Stephens