NEWS BRIEF

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FDA Limits Emergency Use Authorization for Johnson & Johnson Vaccine

The Food and Drug Administration (FDA) recently limited the authorized use of the Johnson & Johnson (J&J)/Janssen COVID-19 vaccine to people age 18 and older for whom other vaccines aren't appropriate or accessible and those who opt for J&J because they wouldn't otherwise get vaccinated. This updated authorization also applies to booster doses.

This change by the FDA is due to the risk of a rare and dangerous condition called thrombosis with thrombocytopenia syndrome (TTS) after receiving the J&J COVID-19 vaccine. TTS is a syndrome of potentially life-threatening blood clots in combination with low levels of blood platelets. Symptoms could begin approximately one to two weeks after receiving the J&J vaccine. The FDA says that 15% of TTS cases have been fatal.

"We recognize that the Janssen COVID-19 vaccine still has a role in the current pandemic response in the United States and across the global community. … [This] action demonstrates the robustness of our safety surveillance systems and our commitment to ensuring that science and data guide our decisions."

- *J&J, in a statement*

What's Next?

As of May 5, the Centers for Disease Control and Prevention (CDC) reports more than 18.7 million doses of the J&J vaccine have been administered in the United States. Of those considered fully vaccinated, 7.7% got the J&J vaccine.

The FDA monitors COVID-19 vaccine safety through passive and active safety surveillance systems in collaboration with the CDC, the Centers for Medicare and Medicaid Services, the Department of Veterans Affairs and other academic and large nongovernment health care data systems.

Individuals should continue to monitor for additional guidance on COVID-19 vaccines from federal, state and local health officials. Kinloch Consulting Group, Inc. will keep you updated on any noteworthy developments.

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