Office of the Secretary Letterhead

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Kansas to Resume Johnson & Johnson Administration

TOPEKA – The Kansas Department of Health and Environment (KDHE) announces that Kansas will resume administration of the Johnson & Johnson (Janssen) COVID-19 vaccine following an announcement on April 23 from the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) encouraging resumption of the vaccine.

"Today, Kansas will resume administering the Johnson & Johnson COVID-19 vaccine," said Governor Laura Kelly. "After a brief pause and a thorough review, the CDC and FDA have determined the vaccine is safe and effective. Whether it's the Johnson and Johnson, Pfizer or Moderna, I strongly encourage every Kansan to get vaccinated as soon as they can."

Johnson & Johnson administration was paused April 13 by the CDC and FDA following reports of recipients in the United States who developed a rare disorder involving blood clots within about two weeks of vaccination. During the pause, the FDA and CDC examined available data to assess the risk of the condition as well as conducted extensive outreach to providers and clinicians to ensure they were made aware of the potential for these adverse events and could properly manage and recognize these events due to the unique treatment required for these blood clots and low platelets, also known as thrombosis-thrombocytopenia syndrome (TTS). Following these reviews, the two agencies have recommended that Johnson & Johnson be resumed in the United States.

Kansas health care providers administering the Johnson & Johnson vaccine and vaccine recipients or caregivers should review the Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) https://www.fda.gov/media/146304/download?utm_medium=email&utm_source=govdelivery and Fact Sheet for Recipients and Caregivers https://www.fda.gov/media/146305/download?utm_medium=email&utm_source=govdelivery, which have been revised to include information about the risk of this syndrome, which has occurred in a very small number of people who have received the Janssen COVID-19 Vaccine.

The federal government will continue studying links between the vaccine and the rare blood clotting disorder. Those who have received the Johnson & Johnson vaccine should contact their health care provider if they have any symptoms and report any illness to the VAERS Reporting System, https://vaers.hhs.gov.

Kansas' next supply of Johnson & Johnson vaccine is anticipated the week of May 3 with 1,700 doses.

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FDA and CDC April 23 Joint Statement: https://www.fda.gov/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough?utm_medium=email&utm_source=govdelivery

Following a thorough safety review, including two meetings of the CDC's Advisory Committee on Immunization Practices, the U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention have determined that the recommended pause regarding the use of the Johnson & Johnson (Janssen) COVID-19 Vaccine in the U.S. should be lifted and use of the vaccine should resume.

The pause was recommended after reports of six cases of a rare and severe type of blood clot in individuals following administration of the Janssen COVID-19 Vaccine. During the pause, medical and scientific teams at the FDA and CDC examined available data to assess the risk of thrombosis involving the cerebral venous sinuses, or CVST (large blood vessels in the brain), and other sites in the body (including but not limited to the large blood vessels of the abdomen and the veins of the legs) along with thrombocytopenia, or low blood platelet counts. The teams at FDA and CDC also conducted extensive outreach to providers and clinicians to ensure they were made aware of the potential for these adverse events and could properly manage and recognize these events due to the unique treatment required for these blood clots and low platelets, also known as thrombosis-thrombocytopenia syndrome (TTS).

The two agencies have determined the following:

- Use of the Janssen COVID-19 Vaccine should be resumed in the United States.
- The FDA and CDC have confidence that this vaccine is safe and effective in preventing COVID-19.
- The FDA has determined that the available data show that the vaccine's known and potential benefits outweigh its known and potential risks in individuals 18 years of age and older.
- At this time, the available data suggest that the chance of TTS occurring is very low, but the FDA and CDC will remain vigilant in continuing to investigate this risk.
- Health care providers administering the vaccine and vaccine recipients or caregivers should review the Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) https://www.fda.gov/media/146304/download?utm_medium=email&utm_source=govdelivery and Fact Sheet for Recipients and Caregivers https://www.fda.gov/media/146305/download?utm_medium=email&utm_source=govdelivery, which have been revised to include information about the risk of this syndrome, which has occurred in a very small number of people who have received the Janssen COVID-19 Vaccine.

CDC's independent Advisory Committee on Immunization Practices met today to discuss https://www.cdc.gov/vaccines/acip/meetings/slides-2021-04-23.html?utm_medium=email&utm_source=govdelivery the latest data on TTS, hearing from the vaccine manufacturer Janssen and the COVID-19 Vaccine Safety Technical (VaST) Subgroup, as well as a risk benefit analysis. ACIP is committed to be vigilant and responsive to additional information that could impact the risk benefit analysis of any of these vaccines. Vaccine safety monitoring will continue and any new information about TTS will be brought to ACIP as needed.

"Safety is our top priority. This pause was an example of our extensive safety monitoring working as they were designed to work—identifying even these small number of cases. We've lifted the pause based on the FDA and CDC's review of all available data and in consultation with medical experts and based on recommendations from the CDC's Advisory Committee on Immunization Practices. We have

concluded that the known and potential benefits of the Janssen COVID-19 Vaccine outweigh its known and potential risks in individuals 18 years of age and older. We are confident that this vaccine continues to meet our standards for safety, effectiveness and quality. We recommend people with questions about which vaccine is right for them have those discussions with their health care provider," said Janet Woodcock, M.D., Acting FDA Commissioner.

"Above all else, health and safety are at the forefront of our decisions," said CDC Director Dr. Rochelle P. Walensky. "Our vaccine safety systems are working. We identified exceptionally rare events – out of millions of doses of the Janssen COVID-19 administered – and we paused to examine them more carefully. As we always do, we will continue to watch all signals closely as more Americans are vaccinated. I continue to be encouraged by the growing body of real-world evidence that the authorized COVID-19 vaccines are safe and effective, and they protect people from disease, hospitalization, and death. I urge anyone with questions about the COVID-19 vaccines to speak with their healthcare provider or local public health department."

Assessment of Available Data

Medical and scientific teams at the FDA and CDC reviewed several sources of information and data related to the Janssen COVID-19 Vaccine to reach today's decision.

Specifically, the agencies assessed reports submitted to the Vaccine Adverse Event Reporting System (VAERS) https://vaers.hhs.gov/reportevent.html?utm_medium=email&utm_source=govdelivery, reviewed the medical literature and considered the information from global regulatory partners about thrombosis with thrombocytopenia that have been reported following use of a similar, yet not identical, COVID-19 vaccine using a virus from the adenovirus family that has been modified to contain the gene for making a protein from SARS-CoV-2.

Update on Adverse Events

On April 13, the FDA and CDC announced https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine?utm_medium=email&utm_source=govdelivery that, out of more than 6.8 million doses administered, six reports of a rare and severe type of blood clot combined with low blood platelet levels occurring in people after receiving the Janssen COVID-19 Vaccine had been reported to VAERS. In these cases, a type of blood clot called cerebral venous sinus thrombosis (CVST) was seen in combination with low levels of blood platelets (thrombocytopenia).

Today, the agencies can confirm that a total of 15 cases of TTS have been reported to VAERS, including the original six reported cases. All of these cases occurred in women between the ages of 18 and 59, with a median age of 37 years. Reports indicated symptom onset between 6 and 15 days after vaccination.

Monitoring for Safety Will Continue

The surveillance systems that are in place to monitor the safety of COVID-19 vaccines authorized for emergency use are working, as demonstrated by both agencies' quick work to identify and investigate these rare, but serious adverse events. The FDA and CDC will continue with these efforts to closely monitor the safety of these vaccines.

Reports of adverse events following vaccination can be made to the Vaccine Adverse Event Reporting System [https://vaers.hhs.gov/reportevent.html?utm_medium=email&utm_source=govdelivery]

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