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Michigan Moving Forward with Administration of Johnson & Johnson Vaccine Based on FDA and CDC Guidance Following Thorough Safety Review

Agencies underscore confidence in vaccine's safety and effectiveness; available data suggest potential blood clots are very rare events

LANSING, MICH. The Michigan Department of Health and Human Services is recommending vaccine providers across the state resume the use of Johnson & Johnson vaccine to vaccinate Michiganders age 18 and older. This recommendation is based on the U.S. Food and Drug Administration (FDA) and the U.S. Centers for Disease Control and Prevention (CDC) recommending to move forward with administering the vaccine. The agencies previously recommended a pause on April 13 while experts conducted a thorough safety review after reports of a rare blood clotting syndrome in some people.

"We are glad to be able to begin administering the Johnson & Johnson vaccine again in Michigan following the thorough review and recommendations of ACIP, CDC and FDA," said Dr. Joneigh Khaldun, chief medical executive and chief deputy for health. "This brief pause indicates there is a robust safety review process in place for these vaccines. These adverse events appear to be extremely rare as nearly 7 million doses of the Johnson & Johnson vaccine have been administered in the U.S. with only 15 cases of this blood clotting syndrome confirmed. We encourage everyone to continue making appointments to be vaccinated with the safe and effective Johnson & Johnson, Pfizer and Moderna COVID-19 vaccines. These vaccines are the way we are going to end this pandemic as quickly as possible and move toward a sense of normalcy."

On April 13, the pause was recommended after reports of six cases of a rare and severe type of blood clot in individuals following administration of the Johnson & Johnson 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).

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 six and 15 days after vaccination.

The two agencies have determined the following:

- Use of the Jonson & Johnson 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) and Fact Sheet for Recipients and Caregivers, 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 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. Reports of adverse events following vaccination can be made to the Vaccine Adverse Event Reporting System.

To find a vaccination location and schedule an appointment, visit the Michigan.gov/Coronavirus website or the CDC COVID Vaccine Finder.

Michigan residents seeking more information about the COVID-19 vaccine can visit Michigan.gov/COVIDvaccine. Information around this outbreak is changing rapidly. The latest information is available at Michigan.gov/Coronavirus and CDC.gov/Coronavirus.

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Additional Resources:

- Fact Sheet for Healthcare Providers Administering Vaccine
- Fact Sheet for Recipients and Caregivers
- CDC Health Alert for Health Care Providers
- Johnson & Johnson Granting EUA Amendment (April 23, 2021)