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PERSONAL HEALTH DIVISION

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CDC and FDA officials: Pause use of Johnson & Johnson

Today the CDC and FDA released a joint statement informing providers of very rare but serious side effects and recommending the U.S. pause use of the Johnson & Johnson (J&J) COVID-19 vaccine out of an abundance of caution. The Benzie-Leelanau District Health Department is following this recommendation and pausing the administration of the J&J vaccine. There is no impact on the use of the Pfizer and Moderna vaccines.

Over 6.8 million doses of the J&J vaccine have been administered in the U.S., but in reviewing data, six cases of extremely rare side effects have occurred after vaccination leading the CDC and FDA to halt the use of the J&J vaccine. The six cases in focus included individuals experiencing a severe blood clot called cerebral venous sinus thrombosis (CVST) after receiving the vaccine. All cases have occurred in women between 18-48 year of age, with symptoms occurring 6-13 days after vaccination.

"At this time the report includes six cases, which is less than one in a million. Given the rarity, it is not surprising that this reaction was not found in the clinical trials. This reminds us that post-authorization surveillance of vaccines is important and effective at finding even rare potential adverse effects," said Dr. Josh Meyerson, Medical Director. "What is currently being reported is not necessarily above the expected rate, but the number and timing after receiving the vaccination deserve more study, and more cases may be found," he said.

Currently, the severe and adverse side effects are extremely rare. For most, post vaccination symptoms after the J&J vaccine include pain at injection site, headache, and flu-like symptoms. Individuals that have received the J&J vaccine and develop severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination should contact their health care provider immediately.

"In accordance with the CDC and FDA guidelines and out of abundance of safety for our community residents, we have paused all administration of the J&J vaccine until we receive further notification," said Lisa Peacock, Health Officer. "We also notified all our partner organizations to do likewise. We will continue to monitor this situation and take all appropriate steps for the safety and health of our community. The pause on J&J administration does not change our vaccination efforts and goals. We will continue with the use of Pfizer and Moderna, adjusting our plans to administer vaccine available with our current allocations," she said.

The CDC plans to convene a meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday to review the cases and asses their significance, and the FDA will review the analysis while investigating the cases. The pause on use of J&J will remain in place during the CDC and FDA data and case review. Health care providers are asked to report adverse reactions to the Vaccine Adverse Event Reporting System here.

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