

State of Louisiana

Department of Health Office of Public Health

DATE: April 13, 2021

TO: Louisiana COVID-19 Vaccination Providers

FROM: Dr. Joseph Kanter & Dr. Frank Welch

SUBJECT: Immediate Pause in the use of Johnson and Johnson COVID-19 Vaccine in the United States.

Following FDA and CDC recommendations, providers in Louisiana should pause administering the J&J COVID-19 vaccine immediately, and all shipments to providers will be temporarily suspended until more information is gathered.

The US Centers for Disease Control and Prevention and the US Food and Drug Administration are recommending that the United States pause the use of Johnson & Johnson's Covid-19 vaccine out of an abundance of caution over six reported US cases of a "rare and severe" type of blood clot.

As of April 12, more than 6.8 million doses of the Johnson & Johnson (Janssen) vaccine have been administered in the U.S. CDC and FDA are reviewing data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the J&J vaccine. 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). All six cases occurred among women between the ages of 18 and 48, and symptoms occurred 6 to 13 days after vaccination. Treatment of this specific type of blood clot is different from the treatment that might typically be administered. Usually, an anticoagulant drug called heparin is used to treat blood clots. In this setting, administration of heparin may be dangerous, and alternative treatments need to be given. CDC will convene a meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday to further review these cases and assess their potential significance. FDA will review that analysis as it also investigates these cases. Until that process is complete, we are recommending a pause in the use of this vaccine out of an abundance of caution. This is important, in part, to ensure that the health care provider community is aware of the potential for these adverse events and can plan for proper recognition and management due to the unique treatment required with this type of blood clot.

Right now, these adverse events appear to be extremely rare. COVID-19 vaccine safety is a top priority for the federal government, and we take all reports of health problems following COVID-19 vaccination very seriously. People who have received the J&J vaccine who develop severe headache, abdominal pain, leg pain, or shortness of breath

Name: Immediate Pause in the use of Johnson and Johnson COVID-19 Vaccine in the United

States.

Date: April 13, 2021

Page 2

within three weeks after vaccination should contact their health care provider. Health care providers are asked to report adverse events to the Vaccine Adverse Event Reporting System at https://vaers.hhs.gov/reportevent.html.

CDC and FDA will provide additional information and answer questions later today at a media briefing. A recording of that media call will be available on the FDA's YouTube channel. Please review the full FDA statement: https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine Please continue to use both the Pfizer and Moderna vaccines as you have been.

The State of Louisiana takes vaccine safety very seriously, and this pause should give the public and providers confidence the system of monitoring and safety checks are working as intended.

If you are a provider with J&J doses, while you should pause administration, please continue to store them in your refrigerator. If you have any remaining questions about the pause, please call the COVID-19 Vaccine Hotline at 1-855-453-0774 or email la.immunization@la.gov.

LDH EOC