LOUISIANA DEPARTMENT OF HEALTH Public Health	**Health Alert Network Message 22-17: FDA Updates Guidance Regarding the Janssen (Johnson & Johnson) COVID-19 Vaccine**
Origination Date: *May 7, 2022*	**Revision Dates (List All Revision Dates):**

FDA Updates Guidance Regarding the Janssen (Johnson & Johnson) COVID-19 Vaccine

On May 5, the Food and Drug Administration (FDA) issued further restrictions regarding who can receive the Janssen (Johnson & Johnson) COVID-19 vaccine due to the ongoing risk of rare but serious blood clots. The FDA said the Janssen vaccine should only be given to adults who cannot receive a different vaccine or specifically request J&J's vaccine because they would not otherwise receive a COVID-19 vaccine.

What is the risk?

In its updated guidance, the FDA said the Janssen COVID-19 vaccine could, on rare occasions, cause thrombosis with thrombocytopenia syndrome (TTS) which may be life threatening.

TTS may involve thrombosis at unusual locations for a thrombus (i.e., cerebral vein, visceral artery or vein, extremity artery, central artery, or vein) or in an extremity vein or pulmonary artery. Among reported cases of TTS following administration of the Janssen COVID-19 Vaccine, symptoms began approximately one to two weeks after vaccination.

Who can still get the J&J vaccine?

The updated FDA guidance says the Janssen vaccine should be given only to adults who cannot receive a different vaccine or specifically request this vaccine.

Instructions to Providers

When it does occur, TTS typically presents in the first two weeks after vaccination with the Janssen product.

Healthcare providers should instruct patients who recently received the Janssen COVID-19 Vaccine and experience shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms (including severe or persistent headaches or blurred vision), or petechiae beyond the site of vaccination to seek immediate medical attention.

The clinical course of TTS following administration of the Janssen COVID-19 Vaccine shares features with autoimmune heparin-induced thrombocytopenia. In individuals with suspected TTS, the use of heparin may be harmful and alternative treatments may be needed.

Do not administer the Janssen COVID-19 Vaccine to individuals with a history of thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine or any other adenovirusvectored COVID-19 vaccine.

The guidance in this HAN is effective immediately.

Full FDA announcement can be found here: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-janssen-covid-19-vaccine-certain-individuals.

Related Information
Fact Sheet for Healthcare Providers Administering Vaccine | May 5, 2022
Fact Sheet for Recipients and Caregivers | May 5, 2022
Frequently Asked Questions on the Janssen COVID-19 Vaccine | February 16, 2022

LDH reminds providers to report possible vaccine-related adverse events to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967.

Any possible severe adverse events (those resulting in hospitalization, death, or persistent disability) should be immediately reported to the Office Public Health (OPH) Infectious Disease/Epidemiology Hotline at 1-800-256-2748.

If you have vaccine related questions, please contact la.immunization@la.gov.

Any member of the public with questions on COVID-19 testing, therapeutics, vaccines, or other related issues can call the Louisiana COVID Community Hotline at 855-453-0774.