

## CDC and FDA Recommendation to Pause Use of Johnson & Johnson COVID-19 Vaccine

### Talking Points:

- CDC and FDA are recommending a pause in use of the Johnson & Johnson/Janssen COVID-19 vaccine after six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the J&J vaccine and in order to prepare the health care system to recognize and treat patients appropriately, to report severe events they may be seeing in people who have received the J&J vaccine.
- As of April 12, more than 6.8 million doses of the Johnson & Johnson 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 from 1:30-4:30pm ET to further review these cases and assess their potential significance.
  - FDA will review that analysis as it also investigates these cases.
- CDC and FDA are recommending a pause in use of the J&J COVID-19 vaccine in order to prepare the health care system to recognize and treat patients appropriately, to report severe events they may be seeing in people who have received the J&J vaccine.
  - This pause also will allow CDC's expert committee to review the situation.
  - 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.

### For individuals receiving J&J vaccine:

- For people who got the vaccine more than a month ago, the risk to them is very low at this time.
- For people who recently got the vaccine—within the last few weeks—they should be aware of any symptoms.
  - If you have received the vaccine and develop severe headache, abdominal pain, leg pain, or shortness of breath, they should contact their healthcare provider and seek medical treatment.
- Importantly, there are three vaccines available. We are not seeing these events with the other two vaccines.

- People who have vaccine appointments with the other two vaccines should continue with their appointment. Our partners will work with those scheduled to receive the J&J vaccine in the days ahead to reschedule.

For clinicians:

- Treatment of this specific type of blood clot, cerebral venous sinus thrombosis (CVST), 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.

Health care providers are asked to report adverse events to the Vaccine Adverse Event Reporting System at <https://vaers.hhs.gov/reportevent.html>.