

Talking Points on Johnson and Johnson (Janssen) Vaccination of Pennsylvanians

- The Pennsylvania Department of Health, on April 13, notified all COVID-19 vaccine providers to pause administering doses of the Johnson & Johnson (Janssen) vaccine until at least April 20 following the recommendation out of an abundance of caution in a joint release from the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA).
- The department is taking these steps as a precaution until the CDC and FDA have time to review six incidents of rare blood clots that occurred within two weeks of receiving Johnson & Johnson/Janssen vaccine.
 - The CDC is convening an emergency meeting of the Advisory Committee on Immunizations Practices on April 14 to further review cases for any details on the significance of this rare occurrence.
- These six cases occurred in women between 18 and 48 who were among the 6.8 million Americans who received the Johnson & Johnson/Janssen vaccine. This announcement shows that the federal oversight process of a vaccine's safety and effectiveness is working, and all steps are being taken to protect Americans.
- While this announcement is challenging, it highlights the vaccine evaluation process.
- The CDC and the FDA are closely monitoring vaccines for safety and effectiveness, and if there is a cause for concern, they will take action because safety is paramount.
- This protocol should give all Pennsylvanians confidence in the safety and
 effectiveness of the Pfizer and Moderna vaccine, and individuals should proceed
 with getting vaccinated as soon as possible to fight the virus, particularly as our
 case counts rise.
- Individuals who have appointments scheduled to receive a Pfizer or Moderna vaccination should keep those appointments. If you are not aware of which vaccine type you are scheduled to receive, be assured that effective immediately, providers will not be administering the Johnson & Johnson (Janssen) vaccine.
- If you received the Johnson & Johnson/Janssen vaccine and have any health concerns, contact your health care provider. People who have received the Johnson & Johnson vaccine who develop severe headache, abdominal pain, leg pain or shortness of breath within three weeks of their vaccination should contact their health care provider. For more information, find the CDC/FDA guidance online here.
- The department also has sent communications to stakeholder groups and others who have received the J&J vaccine as a part of a special vaccination initiative.

For more information about the department's announcement, view the PAcast.



Vaccine providers were sent the following message on April 12:

The Pennsylvania Department of Health, effective immediately, is requesting a pause of administering any doses of Johnson & Johnson/Janssen vaccine until at least April 20, as we await further guidance from the CDC and the FDA.

The Department of Health will not be enforcing the order to administer 80% of doses over 7 days.

It is very important that providers continue to proceed with administration of Pfizer and Moderna vaccine to patients as planned, and explain to patients who may have fears that all of the vaccines are being constantly monitored for safety and effectiveness, and this latest announcement shows this process is working.

We are asking providers who were planning to administer Johnson & Johnson vaccine to individuals to cancel those appointments immediately, or, if possible reschedule those appointments using Pfizer or Moderna vaccine.

It is important that you clearly indicate to patients which vaccine they will be receiving to alleviate any concerns.

The FDA is holding a media briefing at 10 a.m. That can be viewed at https://www.youtube.com/user/USFoodandDrugAdmin.

If you have any questions, please contact the department through the COVID VAX resource account at ra-dhcovidvax@pa.gov.

Thank you for your commitment and dedication to your patients and community during this time. The Department realizes what an extraordinary challenge this pause is for all of you, and we look forward to working through the challenge with you. We remain as a committed partner in vaccinating Pennsylvanians alongside you.