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FDA Restricts Use of Johnson & Johnson Vaccine Over Blood-clot Fears

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On Thursday, the U.S. Food and Drug Administration (FDA) strictly limited the use of the one-shot Johnson & Johnson Covid-19 vaccine to individuals 18 years and older and to those 18 years or older who otherwise will not take one of the two-shot vaccines. A statement from the FDA referenced the risk of what they call "thrombosis with thrombocytopenia syndrome (TTS), a syndrome of rare and potentially life-threatening blood clots."

The J&J vaccine, also referred to as the Janssen vaccine (Janssen is a subsidiary of Johnson & Johnson), was first issued an emergency use authorization in February of last year. As early as April 13 of 2021, the FDA issued a pause on the use of the J&J vaccine to investigate reports of the same type of blood clots. Two weeks later, the FDA rescinded that pause after determining that the potential benefits of the vaccine outweighed the potential risks of blood clots.

"We recognize that the Janssen COVID-19 Vaccine still has a role in the current pandemic response in the United States and across the global community. Our action reflects our updated analysis of the risk of TTS following administration of this vaccine and limits the use of the vaccine to certain individuals," said Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research.

Marks went on to explain that the new restrictions were actually a win for the FDA's monitoring and safety systems.

"Today's action demonstrates the robustness of our safety surveillance systems and our commitment to ensuring that science and data guide our decisions," Marks said.

Among those still approved to receive the J&J vaccine are "individuals who experienced an anaphylactic reaction after receipt of an mRNA COVID-19 vaccine, individuals who have personal concerns with receiving mRNA vaccines and would otherwise not receive a COVID-19 vaccine and individuals who would remain unvaccinated for COVID-19 due to limited access to mRNA COVID-19 vaccines."

The J&J vaccine has been beset by safety concerns since its initial authorization. Originally hailed as an important tool in the war against coronavirus because it only required one shot as opposed to the two shots needed with the Pfizer and Moderna vaccines, health officials eventually found that the multi-dose vaccines reportedly worked better than the one-shot J & J vaccine.

To date, more than 200 million Americans have received the multi-dose mRNA vaccines, while less than

17 million have received the J&J shot.

In December of 2021, a panel for the Centers for Disease Control and Prevention (CDC) concluded that the Pfizer and Moderna mRNA vaccines were "preferred" over the Johnson & Johnson offering due to those same blood-clotting concerns.

"I just cannot recommend a vaccine that is associated with a condition that may lead to death. I think we have other vaccines," said Dr. Pablo Sanchez, one of the CDC's panel members at the time.

Currently, both the FDA and the CDC are continuing to analyze the data on the J&J vaccine on TTS associated with vaccination.

"In an updated analysis of TTS cases following administration of the Janssen COVID-19 Vaccine that were reported to VAERS through March 18, 2022, the FDA and CDC have identified 60 confirmed cases, including nine fatal cases," the FDA statement notes.

The FDA's fact sheet on the J&J vaccine has been updated to include a warning that the use of the drug could prove fatal.

The updated fact sheet also includes warnings for "blood clots with low levels of platelets," as well as a caution about Guillain Barré syndrome, which is described as a "a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis." The fact sheet reports that some who received the vaccine experienced Guillain Barré syndrome within 42 days of getting the shot, although it said incidents of this were considered "very low."

"The Janssen COVID19 Vaccine can cause blood clots with low levels of platelets (blood cells that help your body stop bleeding), which may be fatal," the updated fact sheet reads.

A J&J spokesperson said in a statement, "Data continue to support a favorable benefit-risk profile for the Johnson & Johnson COVID-19 vaccine in adults, when compared with no vaccine."