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FDA Limits Use of J&J Vaccine Over Blood Clotting Disorder, But Experts Say Pfizer, Moderna Shots Pose Similar Risk

The U.S. Food and Drug Administration on Thursday put strict limits on the use of Johnson & Johnson's COVID-19 vaccine, citing the risk of a blood clotting condition, but experts say that Pfizer and Moderna pose similar risks.

By Julie Comber, Ph.D.

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The U.S. Food and Drug Administration (FDA) on Thursday put strict limits on the use of the Johnson & Johnson (J&J) COVID-19 vaccine, citing the risk of a blood-clotting condition the agency described as "rare and potentially life-threatening."

In a statement Thursday, the FDA said the risk of vaccine recipients developing thrombosis with thrombocytopenia syndrome (TTS) after receiving the vaccine "warrants limiting the authorized use of the vaccine."

The FDA said it has identified 60 cases of vaccine-induced thrombosis with thrombocytopenia syndrome, including nine deaths, out of about 18 million doses administered — although the condition is likely underreported.

Women 30 to 49 years old are at the highest risk of TTS from the J&J vaccine, with about eight cases per 1 million doses of vaccine administered, according to the FDA.

According to the latest data from the Vaccine Adverse Event Reporting System (VAERS), between Dec. 14, 2020, and April 29, 2022, there were 13,873 reports of blood-clotting disorders following COVID-19 vaccines in the U.S.

Of those, 6,227 reports were attributed to Pfizer, 4,943 reports to Moderna and 2,662 reports to J&J.

In the U.S., 575 million COVID-19 vaccine doses had been administered as of April 29, including 339 million doses of Pfizer, 217 million doses of Moderna and 19 million doses of J&J.

The agency said the "known and potential benefits" of the J&J vaccine for preventing COVID-19 outweigh the known and potential risks for individuals 18 and older "for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate," or "who elect to receive the Janssen COVID-19 vaccine because they would otherwise not receive a COVID-19 vaccine."

The agency described TTS as "a syndrome of rare and potentially life-threatening blood clots in combination with low levels of blood platelets with onset of symptoms approximately one to two weeks following administration of the Janssen [J&J] COVID-19 vaccine."

The updated restrictions to the Emergency Use Authorization (EUA) of the vaccine, marketed under the Janssen brand, also apply to booster doses, CNN reported.

People who can still get the Janssen vaccine include:

- Those who had a severe allergic reaction to the Pfizer/BioNTech or Moderna mRNA vaccine.
- Those with personal concerns about the mRNA vaccines who would remain unvaccinated unless they can choose the Janssen vaccine.
- Those with limited access to mRNA COVID-19 vaccines.

Symptoms of TTS include shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms (like headaches or blurred vision) or red spots just under the skin called "petechiae" found beyond the site of injection.

Experts question timing, and why just J&J?

Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research, said limiting the authorized use of the Janssen vaccine "demonstrates the robustness of our safety surveillance systems and our commitment to ensuring that science and data guide our decisions."

Marks said:

> "We've been closely monitoring the Janssen COVID-19 Vaccine and occurrence of TTS following its administration and have used updated information from our safety surveillance systems to revise the EUA.
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> "The agency will continue to monitor the safety of the Janssen COVID-19 Vaccine and all other vaccines, and as has been the case throughout the pandemic, will thoroughly evaluate new safety information."

However, Brian Hooker, Ph.D., P.E., Children's Health Defense chief scientific officer and professor of biology at Simpson University, had a different take on the news.

"It seems like the FDA pays lip service to the fact that the spike protein can cause clotting, and to the widespread reports of clotting, by punishing Janssen, who has become the 'whipping boy' of the COVID-19 vaccine manufacturers through the pandemic," Hooker said.

"I believe this is partially because of the limited use of the Janssen vaccine in the U.S. as compared to Pfizer and Moderna," he added.

Hooker said the FDA can limit the use of the J&J vaccine without significantly impacting vaccine distribution overall, "while having the appearance of addressing the myriad vaccine adverse events caused by all the types of COVID-19 vaccines."

As of Thursday, CNN reported only 7.7% of those considered fully vaccinated received the J&J vaccine.

Dr. Pierre Kory, founder and president of Front Line COVID-19 Critical Care Alliance, told The Defender:

> "My only hypothesis is this action is some attempt for the FDA to be able to claim that they took at least some action to protect the safety of the public, akin to 'virtue signaling.'
>
> "Having been a keen observer of their actions throughout the pandemic, I find this action to be completely insufficient and demonstrates a calculated attempt to ensure vaccinations with similarly dangerous vaccines continue."

Dr. Meryl Nass questioned the timing of the FDA's restriction of the EUA.

"Why did the FDA just throw the kill switch on the Janssen vaccine, when it knew of the thrombosis problems since the rollout?" Nass asked.

Nass told The Defender the FDA may have known about the thrombosis problem even before the Janssen vaccine rollout, "since the adenovirus vector platform is known to be associated with thrombosis" for "more than 15 years."

Kory, who noted that all COVID-19 vaccines have had a high rate of adverse events, also questioned the timing of the new restrictions.

"I find the timing of this action to be both irrational and alarming given there is extensive data from around the world, much of it being censored from media and medical journals, that all the COVID-19 vaccines, not just Janssen, have long had unacceptable and diverse toxicity signals — beyond just clotting disorders from numerous pharmacovigilance databases and epidemiological and public health data reports," Kory said.

As far back as April 2021, U.S. and European health officials were investigating whether the J&J COVID-19 vaccines were causing blood clots.

However, there was already mounting evidence the Pfizer and Moderna vaccines could cause similar adverse reactions. U.S. regulatory officials were alerted to this risk as far back as December 2020.

The Centers for Disease Control and Prevention (CDC) in December 2021 recommended the Pfizer and Moderna mRNA COVID vaccines over the J&J vaccine due to the risk of blood clots, despite data showing the Pfizer and Moderna shots also cause blood-clotting disorders.

In January 2021, shortly after the rollout of Pfizer's vaccine in the U.S., The Defender reported on the death of a 56-year-old Florida doctor who developed a blood-clotting disorder after the Pfizer vaccine and died 12 days later.

The Defender also reported on numerous other deaths related to blood-clotting disorders that developed after the Moderna and J&J vaccines.

The J&J vaccine received EUA on Feb. 27, 2021.

On April 13, 2021, the FDA and CDC paused use of the vaccine to investigate six reported cases of TTS.

The agencies lifted the pause only 10 days later, after confirming a total of 15 cases of TTS had been reported to VAERS, including the original six reported cases, out of approximately 8 million doses administered.

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