FDA Limits J&J Shot Over 'Potentially Life-Threatening' Blood Clotting Disorder, Ignores Thousands of Reports to VAERS

In another setback for Johnson & Johnson's (J&J) COVID vaccine, the FDA on Thursday placed strict limits on the use of the one-dose shot, citing concerns over a "rare and potentially life-threatening" blood clotting disorder.

The FDA said the shot should only be given to adults who cannot receive an mRNA vaccine or specifically request J&J's vaccine.

The agency said in a statement it has identified 60 cases of vaccine-induced thrombosis with thrombocytopenia syndrome (TTS), including nine deaths, out of about 18 million doses administered, and the additional cases warrant limiting the "authorized use of the vaccine."

The FDA 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."

Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, said restricting the authorized use of J&J's vaccine, produced by Janssen, "demonstrates the robustness of our safety surveillance systems and our commitment to ensuring that science and data guide our decisions."

Mark's said the data on TTS was gathered from safety surveillance systems like the Vaccine Adverse Reporting System (VAERS). VAERS is the primary government-funded system for reporting adverse vaccine reactions in the U.S. Its biggest limitation is underreporting.

Historically, only 1% of actual vaccine adverse events are reported to VAERS, which means the number of people experiencing severe and potentially fatal blood clotting disorders after receiving J&J's COVID vaccine is likely much higher.

In addition, U.S. health agencies like the FDA and CDC have notoriously limited their diagnostic criteria to reduce the number of adverse events for the disorder they're assessing and have failed to assess the cases of blood clotting disorders reported by those who received Pfizer and Moderna's COVID vaccines entirely.

According to the latest data from 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.

It is unknown how many cases of blood clotting disorders were

reported to other vaccine reporting systems, but it would appear the FDA excluded at least 2,602 cases following the J&J shot from the VAERS system alone.

The FDA's decision to restrict J&J's vaccine comes about five months after the Centers for Disease Control and Prevention recommended Moderna's and Pfizer's vaccines over J&J for booster doses.

In April 2021, federal health agencies paused the distribution of the vaccine to investigate reported cases of blood clotting disorders. But regulators lifted the pause 10 days later and merely added a warning to instructions for its use.

People who spoke out against the vaccine on social media and explained how adenovirus vector vaccines – like the J&J's shot – cause blood clots were censored and their work was labeled as "misinformation."

The government continued to perpetuate a lie for over a year that J&J's COVID vaccine was safe and that only one dose was required to receive protection against the SARS-CoV-2 virus. As it turns out, the shot is neither safe nor effective, and vaccine particles remain in the body months after receiving the injection.

"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," said Dr. Brian Hooker, chief scientific officer at Children's Health Defense and professor of biology at Simpson University.

Despite the restriction, Marks said J&J's vaccine "still has a role in the current pandemic response in the United States and across the global community."

A J&J spokesman said in an emailed statement to CBS News:

“Data continue to support a favorable benefit-risk profile for the Johnson & Johnson COVID-19 vaccine in adults when compared with no vaccine.”