Johnson & Johnson vaccine paused

By AIMEE GREEN and KALE WILLIAMS The Oregonian

Oregon public health officials Tuesday announced the immediate suspension of the Johnson & Johnson COVID-19 vaccine as the Food and Drug Administration recommended putting a "pause" on the treatment over rare health concerns.

"Oregon Health Authority has asked all of the state's vaccine providers to immediately stop administering the Johnson and Johnson vaccine, per the announcement from the U.S. CDC (Centers for Disease Control and Prevention) and FDA this morning," the agency said in a statement. "This is out of an abundance of caution as they review six cases of a rare and severe type of blood clot in women ages 18-48 after vaccination."

The six cases came among nearly 7 million people who have received the Johnson & Johnson vaccine, according to federal officials. One person died and another is in critical condition, according to an FDA official.

Some experts worry that the news will embolden the anti-vax movement. Dr. Paul Cieslak, a senior health adviser at the Oregon Health Authority, is concerned.

"This may give them some additional fuel," Cieslak said. "But I want to point that this was about one in a million vaccine doses administered and we still don't know whether the vaccine was causally related to these side effects.'

On Tuesday, President Joe Biden declared that even with a temporary loss of Johnson & Johnson's oneshot vaccine, there is a huge supply of Pfizer and Moderna vaccines, enough that "is basically 100% unquestionable, for every single solitary American."



Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, speaks alongside White House COVID-19 response coordinator Jeff Zients during a press briefing at the White House on Tuesday.

The advisory by the FDA and CDC — citing a need to investigate reports of rare but potentially dangerous blood clots — was "testimony to how seriously we take safety," said Dr. Anthony Fauci, the nation's top infectious disease expert.

In the opening months of his presidency, Biden has put top priority on a robust response to the virus that has killed 559,000 Americans, with a vaccine campaign in which nearly 50% of adults have received at least one shot.

The CDC's Advisory Committee on Immunization Practices was set to meet Wednesday to delve into the cases of blood clots and "assess their potential significance," according to the CDC and FDA's

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> Dr. Paul Cieslak | senior health adviser at the Oregon Health Authority

statement.

"I think we will know within a couple of days whether the pause is going to be more or less indefinite or whether we'll get the green light," Cieslak said.

The Johnson & Johnson vaccine received emergency use authorization in the U.S. from the FDA in late February with great fanfare, with hopes that its single-dose

and relatively simple storage requirements would speed vaccinations across the country. The Pfizer and Moderna vaccines were not affected by Tuesday's pause.

More than 85,000 Oregonians have received the one-shot Johnson & Johnson vaccine, and the federal government shipped the state 124,400 doses of the Johnson & Johnson vaccine

last week for a total of about 213,000 received. Oregon Health Authority spokesman Tim Heider said the state has distributed the vaccine to 225 locations statewide, and told vaccination providers to hold onto what they have for now. The vaccine can be safely stored at between 36 and 46 degrees Fahrenheit for up to three months, according to Johnson & Johnson.

Heider said it's too early to say how the halt in vaccinations will affect the longterm timelines for getting the vast majority of Oregon's population vaccinated.

At least immediately, the pause on Johnson & Johnson vaccinations isn't expected to dramatically hinder the pace, beyond a slowdown that already was expected. Officials recently

announced they were planning to give far fewer doses of the Johnson & Johnson vaccine over the next few weeks, after problems producing the vaccine in the U.S. and limitations producing it overseas resulted in huge cutbacks in federal shipments to states.

Oregon received 7,300 doses this week and was expecting about 2,000 next week, although numbers weren't yet available for additional doses that also might be sent to pharmacies through the federal retail pharmacy program this week and next.

In a joint statement Tuesday, the CDC and FDA said they were investigating clots in the women who showed symptoms six to 13 days after vaccination. The clots were observed along with reduced platelet counts making the usual treatment for blood clots, the blood thinner heparin, potentially "dangerous."

According to the Oregon Health Authority, none of the six women were from Oregon.

Johnson & Johnson issued a statement advising people who've received its vaccine to contact a health care provider if they experience symptoms of blood clots - including headache, abdominal pain, leg pain or shortness of breath within three weeks of their vaccinations.

Cieslak said people should be on the lookout for a severe headache and not just a mild one. He said even women who've received the vaccine should know they're at "very low risk" for blood clots.

Johnson & Johnson also said it was halting the rollout of its vaccine in Europe, where several countries were planning to start administering the vaccine within days.

The Associated Press contributed to this report.





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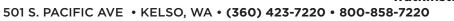




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