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With Few New Clotting Cases, Johnson & Johnson Pause Could Be Lifted Soon

Top federal health officials said in interviews this week that the number of rare blood clotting disorders in recipients of the Johnson & Johnson vaccine has remained small.

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WASHINGTON — Federal health officials are leaning toward lifting their recommended pause on the use of Johnson & Johnson's coronavirus vaccine after finding only a limited number of additional cases of a rare blood clotting disorder among recipients.

Instead, the Food and Drug Administration is considered likely to attach a warning to the vaccine's label to inform health practitioners — and the public — about the exceedingly uncommon, but dangerous possible side effect.

Federal health officials are waiting to act until they hear from a committee of outside experts who advise the C.D.C. The committee is scheduled to meet on Friday to discuss whether to recommend lifting, extending or modifying the pause that was initiated on April 13.

"We know that it's not a good thing to leave the pause going for any longer than it absolutely has to go for," Dr. Peter Marks, the Food and Drug Administration's top vaccine regulator, said Thursday, adding that a protracted pause could contribute to greater vaccine hesitancy. "Once, essentially, the adequate discussion has occurred, we're prepared to move as quickly as we possibly can."

A patient receiving the Moderna coronavirus vaccine on Thursday in New Jersey. James Estrin/The New York Times

When top federal health officials abruptly decided early last week to recommend a temporary halt in the use of the shot, six women had been reported to have had the disorder, a combination of clots in the brain that led to bleeding and low platelets, components of the blood that normally help to heal wounds.

That was fewer than one in a million recipients of Johnson & Johnson's shot in the United States. But officials worried that more cases were hidden or could develop shortly as the new vaccine rolled out.

That fear has not materialized. Dr. Marks and Dr. Janet Woodcock, the F.D.A.'s acting commissioner, said the clotting disorder appeared to be nearly as rare as they had hoped it would be when they recommended the pause.

"We've now received more cases, but it isn't an avalanche," Dr. Woodcock said. "We're not seeing a big surge, which is a great relief."

Dr. Marks declined to specify how many new cases had been confirmed, but said the rate of the disorder was not expected to be higher "in terms of the order of magnitude."

What You Need to Know About the Johnson & Johnson Vaccine Pause in the U.S.

- On April 23, a Centers for Disease Control and Prevention panel of advisers voted to recommend lifting a pause on the Johnson & Johnson Covid vaccine and adding a label about an exceedingly uncommon but potentially dangerous blood clotting disorder.
- Federal health officials are expected to formally recommend that states lift the pause.
- Administration of the vaccine ground to a halt recently after reports emerged of a rare blood clotting disorder in six women who had received the vaccine.
- The overall risk of developing the disorder is extremely low. Women between 30

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Even if the C.D.C.'s advisory committee decides on Friday that the benefits of Johnson & Johnson's single-dose vaccine outweigh its risks, the company will still face manufacturing hurdles at a Baltimore plant that regulators have so far refused to certify. That plant was supposed to deliver the bulk of the nearly 100 million doses Johnson & Johnson had promised to have ready by the end of May.

But it would mean a temporary surge of about 10 million shots that were effectively delayed when the pause was announced. Some state officials had intended to use the one-dose, easily stored vaccine to inoculate college students before the summer or for other transient or hard-to-reach populations, but they had to abruptly shelve those plans.

Dr. Rochelle P. Walensky, the C.D.C. director, said in an interview on Wednesday that federal officials had found "needles in haystacks," an indication of how thorough the government's oversight was. "We would like to make a decision quickly after ACIP," she said, using the acronym for the expert panel, the Advisory Committee on Immunization Practices. "America and the world are interested in moving forward."

Johnson & Johnson's first vaccine shipment from Kentucky in March. Pool photo by Timothy D. Easley

European regulators, presented with similar concerns, recommended this week that the vaccine's rollout continue as long as a risk warning was added to the product. If American officials follow suit, they will revert to a precaution that they had considered early on.

Before the pause was initiated, F.D.A. officials had drafted a brief warning about rare, but possible blood clots to attach to the section of the vaccine's emergency use authorization describing its possible side effects.

Doctors had prescribed the wrong treatment for several women with the clotting disorder who received the vaccine, possibly worsening their conditions. With C.D.C. input, officials expected that the unusual warning for doctors about the need for specialized treatment and consultation could be issued as early as last Tuesday, April 13, according to people who heard about the planning.

But in a meeting at 8 p.m. Monday, April 12, the plans changed. Dr. Walensky, Dr. Woodcock and other top health officials said they had decided that a temporary halt in the use of the vaccine would give doctors and federal scientists more time to understand any possible links between the vaccine and the clots.

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Some federal health officials felt the move — one of the Biden administration's most consequential interventions so far in its pandemic response — was a hasty overreaction in the middle of the nation's vaccination campaign.

Just a day after the Food and Drug Administration recommended the pause, Dr. Doran Fink, a key vaccine regulator with the agency, suggested to the C.D.C.'s advisory panel that if doctors and recipients were given enough information, the vaccine could be brought back into play while researchers continued to study the potential risks.

"Our current thinking is that this risk could be managed by inclusion of warning statements," Dr. Fink told other experts at the first advisory meeting last Wednesday.

His remarks were unusually explicit, according to Dr. William Schaffner, an infectious disease expert and a consultant to the panel.

The deliberations underscored how difficult drafting policy in the middle of a public health emergency can be. Scientists must make decisions that can mean the difference between life or death while still gathering data on tight deadlines.

Dr. Woodcock acknowledged on Thursday differences of opinion within the Food and Drug Administration about the benefits of a temporary halt versus the risks of additional coronavirus infections if the vaccine were temporarily shelved.

As European regulators and C.D.C. and F.D.A. officials grappled with reports of the rare clotting cases in the weeks before the pause, regulators saw an unmistakable similarity in the cases in the United States. All had occurred within one to three weeks of vaccination and they were clustered in women under 50.

One woman in Virginia had died, and three other women had been hospitalized, two of them in intensive care.

Dr. Woodcock said that a warning would have been insufficient if there was in fact a high rate of cases, like one in every 25,000 or 50,000 young women. "We would be putting people at risk when we didn't have that information," she said, and pushing ahead amid uncertainty "could actually cause a worse reaction in the population."

Some public health experts did express concern, though, given the daily number of new infections and the number of Americans who could have been protected over the past 10 days had the vaccine remained in use.

"It's just very hard for me to see, even if you multiply the number of cases by five or by 10, that you come to the conclusion that this is not a good thing to do, giving you the vaccine," said Dr. Ezekiel J. Emanuel, a professor of medical ethics and health policy at the University of Pennsylvania.

The decision to recommend the pause was "not cut and dry," Dr. Walensky said, but she added that it had "overwhelming support within and outside the agency." She said that the vaccine "was going to take a hit regardless given that we had to put the warning on it."

Dr. Anthony S. Fauci, the government's top infectious disease expert, said in an interview this week that his colleagues had made the right call. Public health emergencies often require charged policy choices with incomplete data, he said.

"It's so painful or difficult when there is not an absolutely right or absolutely wrong way to come down on something," Dr. Fauci said. "It's just a gray zone."

But, he added, "a decision has to be made."

Dr. Matthew Wynia, an ethicist and infectious disease physician at the University of Colorado, said that health officials faced a frightening trade-off in choosing between a pause and warning: They would know only hypothetically the lives a pause may have cost, but they would know exactly who may have suffered or died from clots.

Because of how unusual this disorder is, Dr. Wynia said, a typical warning to physicians would not have grabbed as much attention and "not have made the impact this did."

But Dr. Steven Joffe, a bioethicist at the University of Pennsylvania, said that a warning could have sufficed, at least initially, while a pause could be a problematic signal to the rest of the world "to maybe be skeptical of the J. & J. vaccine, when it's such an important piece of the puzzle." He added that physicians would most likely have registered suitable alarm from a warning about a product in extraordinary demand.

Inside the C.D.C.'s Atlanta headquarters over the past week, officials studied and judged an expected uptick in reports of clotting, Dr. Walensky said.

The C.D.C. had also devised models to measure the effect of the pause on people who might not get vaccinated without the Johnson & Johnson shot available — a "risk-benefit at a population level" that aimed to help scientists understand the "true value of that vaccine," Dr. Walensky said.

Some early polling about the pause suggested that Americans saw the move as a sign that the government was responsibly monitoring the coronavirus vaccines. But one poll released by Boston Children's Hospital showed that Americans who wanted to get vaccinated were now significantly less willing to get the Johnson & Johnson shot.

"It took only six cases to do this," said Dr. Joseph Kanter, the top health official in Louisiana, where other vaccines had to be substituted for Johnson & Johnson's at homeless vaccination events in New Orleans, at faith organization vaccine drives and on college campuses. "Anyone who has questions or concerns about how serious safety is taken should look at this as an example that safety is paramount."

He said that rescheduling appointments had been a "surmountable challenge," and that the pause meant state officials would just "have to work a little bit harder to get people back."

Dr. Kanter and other state officials have been surprised by the shot's popularity with people wanting a single-dose vaccine, and the officials are eager to use it as demand for vaccinations may flatline.

"We're clearly at the stage now when we have more than enough vaccine. The demand is clearly not as much as the supply at this point," said Dr. José R. Romero, Arkansas' top health official and the head of the C.D.C. vaccine advisory panel. "This vaccine would help get those persons on the borderline."