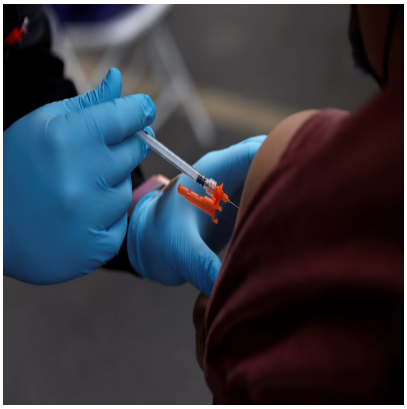


FDA Postpones Decision on Pfizer COVID-19 Vaccine for Young Children

Description

USA: U.S. drug regulators on Feb. 11 announced they are pushing back a decision on whether to authorize Pfizer's COVID-19 vaccine for children as young as 6 months old.

The Food and Drug Administration (FDA) had planned to consult its vaccine advisory committee on Feb. 15 on the jab for young children and could have granted emergency use authorization (EUA) for the shot within hours of the meeting. But that plan has changed, based on a preliminary assessment of data Pfizer sent on Feb. 1.

FDA officials now believe that they cannot clear the shot for children aged 6 months to 4 years until they receive data from an ongoing trial examining a three-dose regimen for the age group.

"The data that we saw made us realize that we needed to see data from a third dose, as in the ongoing trial, in order to make it the term determination that we could proceed with doing an authorization," Dr. Peter Marks, the director of the FDA's Center for Biologics Evaluation and Research, told reporters on a call.

"I think parents can feel reassured that we have set a standard by which we feel that if something does not meet that standard, we can't proceed forward," he added.

Multiple panel members declined interview requests before Friday's announcement. Dr. Eric Rubin, a member who serves as editor-in-chief of the New England Journal of Medicine, told The Epoch Times in an email that it was "difficult to draw any conclusions at this point" because members had not seen the data.

Every American aged 5 or older can currently get Pfizer's two-dose primary regimen.

The trial testing the regimen on young children, which Pfizer and its partner, BioNTech, are running, showed the two doses triggered an adequate immune response for children aged 6 months to 1 year, but did not in children aged 2 to 4, the companies announced in December 2021. They said at the time that they planned to test a three-dose regimen for toddlers.

But the FDA soon after asked the companies to send data over due to concerns about the spike in

COVID-19 cases and hospitalizations among all age groups driven by the Omicron variant of the CCP (Chinese Communist Party) virus, which causes COVID-19. Pfizer and BioNTech then, on Feb. 1, requested the EUA for the new youngest age group.

COVID-19 cases, particularly those caused by Omicron, in children rarely lead to severe disease or death, but some parents and health groups have been pressuring the FDA to greenlight the jab for the this new age group, arguing that doing so would help protect the children against infection and hospitalization.

Critics note that the Pfizer vaccine and the two others authorized for use in the United States have gone down in effectiveness against more recent strains, especially Omicron, and that getting toddlers vaccinated is not worth the risk, given the possible side effects.

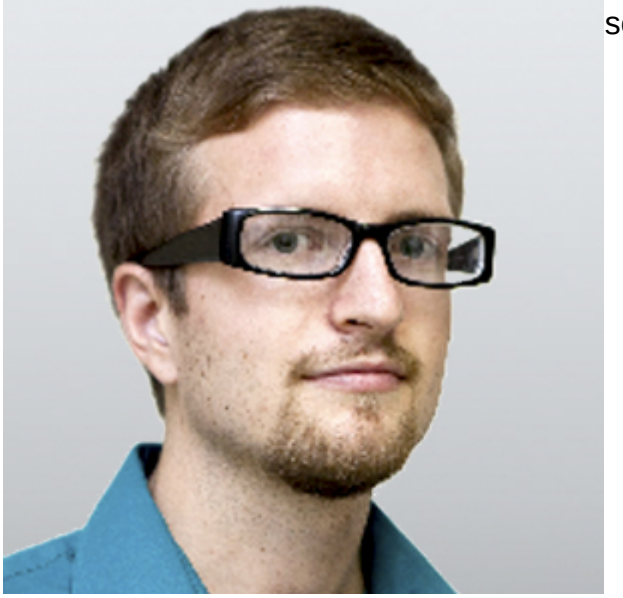
Pfizer and BioNTech in a joint statement said the companies plan to extend the rolling submission of data for the EUA request.

“Given that the study is advancing at a rapid pace, the companies will wait for the three-dose data as Pfizer and BioNTech continue to believe it may provide a higher level of protection in this age group,” they said. “The extension allows the FDA time to receive updated data on the two and three-dose regimen, conduct a thorough evaluation of it and facilitate a robust, public discussion.”

An independent monitoring committee overseeing the study supports continuing it and believes “that the data collected to date indicate the vaccine is well tolerated and support a potential three-dose regimen,” the companies also said.

The updated data is expected in early April.

“Once the next tranches of data come in, we will be looking at them in an expeditious manner,” Marks said. The decision could very well be based on actual clinical data as opposed to the immunobridging



ses among children to immune responses in a set of adults,

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