US weighs authorizing Pfizer COVID vaccine for younger children

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A high level medical panel of US government advisors was meeting Tuesday to decide whether to authorize the Pfizer COVID-19 vaccine in five-to-11-year-olds, likely paving the way for younger children to get their shots within weeks.

If, as expected, the independent experts convened by the Food and Drug Administration (FDA) vote in favor, it will set in motion actions leading to 28 million more Americans becoming eligible for immunization.

Opening the meeting, senior FDA scientist Peter Marks said younger children were "far from being spared harm of COVID-19," adding that, in this group, there had been 1.9 million infections and 8,300 hospitalizations, roughly a third of which required intensive care.

There have also been around 100 deaths, making it a top 10 leading cause of death, he added.

The question before the experts: based on the scientific evidence available, do the benefits of the two-dose vaccine, given three weeks apart, outweigh the known risks.

An analysis by Pfizer posted by the FDA before the meeting showed the vaccine—given at 10 micrograms instead of 30 micrograms as in older groups—was 90.7 percent effective at preventing symptomatic COVID-19, and there were no serious safety issues.

The FDA also carried out a detailed a risk-benefit analysis, which indicated the agency's scientists believe the benefits exceed the most worrying potential side-effect for this age group: myocarditis, or heart inflammation.

FDA scientist Hong Yang presented a model that showed at current infection rates, the vaccine would prevent far more hospitalizations from COVID than they might cause from myocarditis.

If community transmission was brought down to very low levels, this may change—but even then vaccination might be worthwhile because of long term risks linked to non-hospitalized cases, she added.

These include multisystem inflammatory syndrome in children (MIS-C), a rare but highly serious post-viral complication, which has affected more than 5,000 children of all ages and claimed 46 lives.

William Gruber of Pfizer added there were wider societal benefits too.

For example, children likely play an important role in transmission and vaccinating children can help reach herd immunity.

"Vaccination will help ensure in-person learning which is critical for childhood development by limiting community spread and school outbreaks," he added.

Myocarditis risk

In its clinical trial, Pfizer evaluated safety data from

a total of 3,000 vaccinated participants, with the most common side-effects mild or moderate, including injection site pain, fatigue, headache, muscle pain and chills.

There were no cases of myocarditis or pericarditis (inflammation around the heart), but there were not enough study volunteers to be able to detect highly rare side-effects.

Matthew Oster, a researcher at the Centers for Disease Control and Prevention (CDC), gave a presentation on what is known so far about the side-effect among groups already eligible for vaccines.

Of 877 vaccine-induced myocarditis cases in under 29s, 829 were hospitalized, according to official data. The vast majority were discharged but five remain in intensive care.

The rate of the side-effect will probably be lower in the five-to-11 age group than among adolescent males, because it is thought to be linked to testosterone.

The panel will have to weigh this theoretical risk against preventing COVID, which may cause more frequent and severe myocarditis.

The meeting comes as the United States is emerging from its latest wave driven by the Delta variant.

But infections remain high in northern states such as Alaska, Montana, Wyoming and Idaho, which are experiencing colder weather and have lagging vaccination rates.

Overall, 57 percent of the total population is now fully vaccinated.

Vaccine confidence has risen in recent months, but the United States remains behind every other G7 nation in percent of population fully vaccinated.