Moderna Asks FDA to Authorize COVID Vaccine for Infants and Kids Under 6 After Changing Efficacy Number

Moderna announced Thursday it has submitted a request for Emergency Use Authorization (EUA) of its COVID vaccine mRNA-1273 for children 6 months to under 2 years and 2 years to under 6 years of age to the U.S. Food and Drug Administration (FDA).

"We believe mRNA-1273 will be able to safely protect these children against SARS-CoV-2, which is so important in our continued fight against COVID-19 and will be especially welcomed by parents and caregivers," Stéphane Bancel, CEO of Moderna said in a press release.

The company claimed data showed "a robust neutralizing antibody response" and "a favorable safety profile."

Yet, Moderna's KidCOVE study cited in its press release shows

Moderna's COVID-19 vaccine failed to meet the FDA's minimum efficacy requirements for EUA in the 2 to under 6 age group, and barely surpassed the agency's 50% efficacy requirement in the 6-month to 2-year age group after the vaccine maker literally changed its analysis to meet the guideline.

In the younger age group, Moderna on Thursday said the effectiveness of its vaccine was 51%. In the older age group, vaccine efficacy was only 37% – substantially lower than the FDA's requirement.

These are different efficacy numbers than those the company reported just last month.

In a March 23 press release, Moderna said its vaccine in the 6-month to 2-year age group was only 43.7% effective. In the older age group, the company said its vaccine was 37.5% effective.

In fact, The New York Times on Tuesday said Moderna's COVID-19 vaccine "proved disappointing" because it was only 40% effective, and a top official with Moderna said she expected a booster to be necessary.

To explain changing the efficacy to 51%, Moderna in Thursday's press release said:

> *"The previously announced results included a supportive preliminary efficacy analysis on cases mostly collected during the Omicron wave, including home testing for COVID-19.*
>
> *"When the analysis is limited only to cases confirmed positive for SARS-CoV-2 by central lab RT-PCR, vaccine efficacy remained significant at 51% (95% CI: 21-69) for 6 months to <2 years and 37% (95% CI: 13-54) for 2 to <6 years."*

Moderna said it still needs to complete its EUA filing by sending final datasets to the FDA, which the company said will

not happen until next week.

Dr. Madhava Setty, responding to the news, said Moderna is not providing the data needed to calculate the risk-benefit of its COVID-19 vaccine.

"They're proud of the immune response but the FDA has already concluded in its advisory committee meeting on April 6, that immune response means nothing," Setty said. "We need actual outcomes."

Setty, a board-certified anesthesiologist and senior science editor for The Defender, explained:

> *"In order for parents to understand risk vs. benefit for their child, they need to know exactly how many children got COVID-19 in Moderna's study. This is the only way to calculate how many children need to get jabbed to prevent a single case.*
>
> *"By offering us only vaccine efficacy numbers, Moderna and CNN are implying that there is no associated risk for their child, which we know is untrue."*

Setty noted that 51% effectiveness barely meets the FDA's minimum efficacy under EUA and children were followed for only 28 days.

"New York data show vaccine effectiveness against SARS-CoV-2 in the 5 to 11 age group plummets within seven weeks to 12%," Setty said.

"Here, we're looking only at the first four weeks. Although data from New York were in a different age group using a different mRNA vaccine, the effectiveness was remarkably similar after four weeks. Why wouldn't we expect that the same thing is going to happen?"

According to CNN, the most common reactions reported during the study were pain at the injection site and fever. There were no cases of heart inflammation or myocarditis, according to Moderna.

"With only 2,500 children included in the youngest age group and the rate of myocarditis at 1 in 2,700 in a higher at-risk age group, according to a recent Hong Kong study, a trial this small is not going to pick up myocarditis," Setty said. "Saying there were no cases of myocarditis is hardly reassuring. The study is not powered to pick it up."

According to ClinicalTrials.gov, the results of Moderna's study have not been posted and the study is not scheduled to be completed until Nov. 12, 2023.

FDA requires 50% efficacy in preventing or decreasing severe disease for EUA

According to the FDA, for a COVID-19 vaccine to receive EUA, it must be at least 50% effective at preventing or decreasing the severity of the disease.

Guidelines for COVID-19 vaccines were released during a June 30, 2020 briefing with the Senate Committee on Health, Education, Labor and Pensions, during which senators sought assurances from former FDA Commissioner Stephen Hahn, Dr. Anthony Fauci and other top health officials that the expedited speed of development wouldn't compromise the integrity of the final product.

According to Moderna, its KidCOVE study is a "randomized, observer-blind, placebo-controlled study to evaluate the safety, tolerability, and immunogenicity of two doses of mRNA-1273 given to healthy children 28 days apart."

The study population was divided into three age groups (6 to <12 years, 2 to <6 years, and 6 months to <2 years). In the study, efficacy could be evaluated only if enough cases

accrued.

Approximately 6,700 participants 6 months to under 6 years old were enrolled in the study with 2,500 in the youngest age group.

In its March 23 press release, Moderna said using the Phase 3 COVE study COVID-19 definition, vaccine efficacy in children 6 months to 2 years was 43.7% and vaccine efficacy was 37.5% in the 2 years to under 6 years age group. The company defined "statistically significant" as a lower bound on the 95% confidence interval, which is greater than 0.

"The majority of cases were mild, and no severe COVID-19 disease was observed in either age group," the company added. "The absence of any severe disease, hospitalization or death in the study precludes the assessment of vaccine efficacy against these endpoints."

Dr. Meryl Nass, an internist and member of the Children's Health Defense scientific advisory committee, said the FDA told manufacturers it needed 50% efficacy with a lower bound of 30% to issue COVID-19 vaccines under EUA. Yet, Moderna produced no evidence its vaccine prevents severe disease, hospitalization or death from COVID-19.

Nass explained:

> *"The efficacy of this vaccine was under 50% for both age groups and their lower bound is 0, well below the 30% specified by FDA, and indicating a reasonable chance the vaccine may provide no benefit at all.*
>
> *"There were no cases of severe disease, hospitalization or death from COVID-19 in the 6,700 children studied from 6 months through 6 years. Since these are the only endpoints (dreaded COVID-19 effects) that everyone wants to prevent, there is no evidence whatsoever that the Moderna vaccine*

> *prevents them."*

Nass said there is "no need to vaccinate small children with an experimental vaccine that has been shown to prevent only the equivalent of a cold" and the FDA cannot justify issuing an EUA or license for the Moderna shot for children 6 and under.

Nass said:

> *"The vaccine fails to meet the standards FDA published, there is no evidence it prevents severe disease and its safety is a mystery. They did not provide any reasonable justification for what they did – for doubling the sample size or extending the trial – nor did they say how many weeks or months after vaccination they got this result.*

> *"How many kids actually got sick in the control group versus the vaccinated group? If they were trying to convince us this data should have been provided."*

"Will FDA con parents into thinking they are giving their children durable COVID-19 protection by issuing an EUA and permitting broad use of Moderna's vaccine in the youngest children?" Nass asked.

"We continue to ignore the 'E' in 'EUA,'" Setty said. "Despite it being deployed on thousands of children, this therapy did not prevent death. It didn't prevent hospitalization. It didn't prevent severe disease. It modestly prevented the sniffles. Where is the emergency?"

Moderna making last-ditch effort to

get jab under EUA

According to the most recent data from the Centers for Disease Control and Prevention, out of 2,311,870 children under 4 who had COVID-19, 475 deaths were reported, accounting for 0.1% of all COVID-19 deaths.

Dr. Michelle Perro, pediatrician and co-author of "What's Making Our Children Sick?" said this may be "Moderna's last-ditch effort to get their COVID jab approved for EUA for children 6 years younger, avoiding indemnification," yet there are "obvious flaws in this last desperate push."

Perro explained:

> *"Firstly, there is no emergency. Secondly, and more importantly, children do not have morbidity or mortality from COVID-19. As more and more people have become cognizant of the fact that their children were subjected to an unknown, dangerous gene therapy, the resistance to this failed experiment grows.*
>
> *"The literature is shedding light on the children now with chronic cardiac disorders, sequelae from clotting issues and bizarre neurologic symptoms – an incomplete list – who were sacrificed.*
>
> *"The only issue now facing practitioners caring for children is how to help those injured by the genetic experiment and hope that the damage will not lead to long-term health consequences."*

No COVID-19 vaccine has been authorized for children younger than 5 in the U.S. and a timeline for potential authorization is not yet clear.

The House Select Subcommittee on Coronavirus Crisis on Tuesday

asked the FDA for a status update on COVID-19 vaccines for children under 5. This could change how the FDA handles Moderna's request.

In a letter to FDA Commissioner Dr. Robert Califf requesting a staff briefing, committee members said "millions of young children still remain unprotected because no vaccine has yet been authorized" for this age group.

A top FDA official on Tuesday told The New York Times the agency had not cleared a COVID-19 vaccine for the youngest age group because Pfizer and Moderna had not finished their applications for authorization.

The agency said last week it was considering holding off on reviewing Moderna's request to authorize its COVID-19 vaccine for children under 5 until it has data from Pfizer and BioNTech on their vaccine for children, pushing the earliest possible authorization of a vaccine from May to June.