Moderna Shuts Down mRNA RSV Vaccine Trial in Babies After Shots Linked to Severe Side Effects, FDA Document Reveals

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Moderna halted its clinical trial of experimental mRNA vaccines for respiratory syncytial virus (RSV) in babies after the shots were linked to severe side effects.

The U.S. Food and Drug Administration (FDA) disclosed this week in a briefing document that rather than protecting babies as anticipated, the vaccine likely caused higher rates of severe RSV illness among the vaccinated babies enrolled in the Phase 1 clinical trials.

The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet Thursday "to discuss considerations for RSV vaccine safety in pediatric populations" based on Moderna's clinical trial data.

Although the FDA never cites Moderna by name in the document as the

company that made the vaccine in question, the agency lists the investigational vaccines, mRNA-1345 and mRNA-1365, and describes trial outcomes.

The FDA document also stated that enrollment is now on hold for all investigational trials for RSV vaccines for infants and toddlers under age 2 and children ages 2 through 5 who haven't previously had RSV illness.

> After safety signal in @moderna_tx's trial forced vaccinemaker to end study@US_FDA disclosed today that enrollment of young children is now
>
> "on hold for all clinical studies of RSV vaccine candidates under U.S. IND"https://t.co/6IWXgmDCz9 pic.twitter.com/sAWzMSOUsk
>
> — Alexander Tin (@Alexander_Tin) December 10, 2024

In September, Moderna announced it had put the brakes on its plan to roll out its mRESVIA RSV vaccine for babies, "based on emerging clinical data."

This is not the first time that an attempt to develop an experimental RSV vaccine for children caused severe illness. The FDA said a formalin-inactivated RSV vaccine trialed in the 1960s led to two toddler deaths, and 80% of vaccine recipients required hospitalization for severe RSV.

The illnesses were attributed to vaccine-associated enhanced respiratory disease (VAERD) — a phenomenon that occurs when vaccination promotes immune responses that exacerbate the disease caused by subsequent infection with the pathogen the vaccine was meant to protect against.

The trials were halted in 1967, and clinical RSV vaccine research stalled until recently.

In 2023, the FDA gave Moderna the green light to move ahead with its clinical trial, also called the Rhyme Trial, to test the safety and immunogenicity of its two investigational mRNA RSV drugs in children ages 5-23 months.

The study received approval after the FDA fast-tracked Moderna's investigational RSV vaccines in 2021, a process that speeds up the development and approval of a drug.

Results shared in the briefing document indicate that Moderna's investigational vaccines also triggered a potential VAERD safety signal in small children.

Commenting on the briefing document, Dr. Meryl Nass, an internist, told The Defender:

"FDA is trying to cover itself, to avoid claims of negligence. It should have anticipated VAERD, because it happened before in RSV trials — and killed babies — and because it is happening now with the COVID vaccines, which, after roughly 6 months, depending on age and dose, make the recipient more likely to get COVID."

In May, the FDA approved Moderna's mRNA-1345, marketed as mRESVIA, for adults age 60 and over. It is Moderna's only product, other than the COVID-19 vaccines, approved for market.

The FDA approved the drug without input from VRBPAC, which typically makes recommendations about such drugs because the agency said in its approval letter that it didn't see any "concerns or controversial issues" that would make input necessary to the approval process.

Nass said that "FDA now has to worry about whether the adult RSV vaccine also may cause disease enhancement in the elderly, or other problems not appreciated or ignored in the clinical trials."

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Severe risks 'may not be over'

Moderna's trial tested two mRNA RSV vaccines at once. Some babies received mRNA-1345, or mRESVIA, and others received mRNA-1365, designed to protect against RSV and human metapneumovirus (hMPV).

A third group received a placebo, although the study noted that the placebo could be Nimenrix — a meningococcal vaccine — rather than a true placebo.

The parent information sheet for the Rhyme Trial informed parents of the VAERD problems in the original RSV trials but said, "Experts believe that there is very little risk of this happening with the mRNA-1345 or mRNA-1365 vaccines in this study," The Defender reported in an earlier investigation.

In its briefing document, the FDA reported that in the trials five (12.5%) babies in the vaccine groups — who had received one or two doses of a three-dose schedule — developed severe or very severe RSV, compared with only one case (5%) in the placebo group.

They also found that in 26.3% of vaccinated participants who had symptomatic RSV, the illness progressed to become severe compared with only 8.3% in the placebo group.

The report also said that responses to the prophylactic antibody Beyfortus (nirsevimab) were "blunted" in babies who were vaccinated with the mRNA shots.

Moderna was made aware by July 17 of at least two positive RSV lower respiratory tract infections in the study, triggering a safety signal. The

vaccine maker paused the study and no more babies were enrolled.

As more surveillance data accrued and RSV season continued, more evidence emerged of an "imbalance" between the vaccinated and unvaccinated babies in rates of severe RSV. Two babies in the vaccine cohort were also hospitalized for hMPV.

The risks for babies who participated in the trial may not be over, according to Dr. Peter Selley, a retired U.K. general practitioner who has closely followed the development of these vaccines.

"The bottom line is that this is a ticking bomb, as the toddlers started having serious illness in July, which points to the Southern Hemisphere," he said. "In the Northern Hemisphere, the RSV season is still not in full swing. This must be very worrying for the parents of the children in this trial."

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Other RSV vaccines raise concerns

RSV is a common respiratory virus that usually causes mild cold-like symptoms, but in some cases can lead to hospitalization and death in infants and the elderly.

By age 2, 97% of all babies have been infected with the RSV virus, which

confers partial immunity, making any subsequent episodes less severe.

The disease burden for infants can be serious. In the U.S., RSV infection is the leading cause of infant hospitalization among those younger than 6 months, although a very small percentage of children with the virus will die.

According to a CDC study analyzing RSV deaths in infants between 2005 and 2016, there was a total of 314 deaths in children under age 1, or 25 on average per year, Nass reported, citing 2021 CDC data. Only 17 of those deaths per year listed RSV as the underlying cause of death.

Yet, in the last few years, there has been a rush to get RSV vaccines to market. So far all of the vaccines have raised concerns about serious side effects.

Before licensing Moderna's mRNA RSV vaccine for older adults last year, the FDA in May 2023 licensed GSK's Arexvy and Pfzer's Abrysvo, non-mRNA vaccines that both won approval for adults ages 60 and older or some younger high-risk adults.

Both vaccines showed serious neurologic side effects during the clinical trials and then again in post-licensing studies. Growing evidence of adverse events associated with the RSV vaccine, including the documented risk of Guillain-Barré syndrome, led the CDC to walk back its recommendations in June, narrowing the recommended age group for RSV vaccination from adults 60 and older to adults 75 and older.

"And in adults, the vaccine is intended to prevent colds!" Nass said. "So the risk-benefit ratio was poor to begin with. Now FDA will need to see if VAERD occurs in vaccinated adults."

Both pharmaceutical giants also ran clinical trials for their respective vaccines in pregnant women. GSK stopped the development of its RSV

vaccine for pregnant women when it found a safety signal for preterm births among vaccinated women.

Pfizer's own clinical trial data for Abrysvo showed elevated rates of preterm birth among vaccinated women, but the higher rates were not statistically significant, Pfizer said.

Still, the FDA limited approval of the vaccine for women in weeks 32-36 of their pregnancy to reduce risk and mandated post-market follow-up studies for both preterm birth and eclampsia.

Last year, the FDA approved and the CDC recommended Beyfortus, a monoclonal antibody shot produced by pharma giants Sanofi and AstraZeneca, for newborn infants whose mothers hadn't been vaccinated during pregnancy.

Several infant deaths — 12 in all — were reported during the clinical trial for Beyfortus. The FDA claimed all 12 were "unrelated" to the antibody.

Documents obtained from the CHD through a Freedom of Information Act request also revealed that at least two infants died the day they received Beyfortus after the drug was placed on the market.

The FDA in 2023 also authorized Pfizer to conduct clinical trials of its Abrysvo in children ages 2-18 in its Picasso trial. The clinical trials website indicates that Phase 1 of the study concluded in February, but no results were ever made public.

Neither Pfizer nor any of the clinics sponsoring the Picasso trials have responded to The Defender's request for information about that trial.