FDA Approves Moderna's mRNA RSV Vaccine — With No Input From Independent Advisers

The FDA said it bypassed input from the agency's independent advisers because it didn't see any "concerns or controversial issues." Moderna is running at least 11 clinical trials for its new mRNA RSV drug on other demographic groups, including young children, adolescents and healthy adults.

7 min. read · View original

The U.S. Food and Drug Administration (FDA) last week approved Moderna's mRNA respiratory syncytial virus (RSV) vaccine for adults age 60 and older.

The FDA approved the drug without input from the agency's independent vaccine advisory committee, which typically makes recommendations about such drugs, because the FDA didn't see any "concerns or controversial issues" that would make input

necessary to the approval process, the agency said in its approval letter.

Moderna is running at least 11 clinical trials for its new mRNA RSV drug on several other demographic groups, including young children, adolescents and healthy adults.

The vaccine, marketed under the name mResvia, is Moderna's second-ever FDA-approved drug. It uses the same mRNA platform as its COVID-19 Spikevax vaccine.

"The FDA approval of our second product, mRESVIA, builds on the strength and versatility of our mRNA platform," said Moderna CEO Stéphane Bancel.

The Centers for Disease Control and Prevention (CDC) must recommend the drug before it can be used. The CDC's advisory committee will discuss and vote on the vaccine at its meeting next month.

If approved, the vaccine will provide a second revenue stream for Moderna, whose first-quarter sales fell 91% compared with same-quarter sales in 2023.

The company said it expects to launch the vaccine in time for the 2024 fall vaccination season.

The FDA's approval of Moderna's mRNA RSV vaccine comes a year after the agency approved

GSK's Arexvy and Pfizer's Abrysvo RSV vaccines for the same age group.

Abrysvo also is approved for pregnant women. Pfizer is seeking approval for its drug for adults ages 18 and older and is testing it on children and teens. GSK is seeking approval for Arexvy for people 50 and above and expects a response this month.

Bancel said Moderna's shot has an advantage over the RSV vaccines now on the market because it comes in a pre-filled syringe, making it faster to administer and cutting the risk of administration errors.

Moderna said it hopes to capture part of what it predicts will be a $10 billion market for RSV vaccines, especially given its post-pandemic plummet in profits.

The company also announced last week that it is in talks with the U.S. government to fund late-stage trials of its mRNA bird flu vaccine.

Experts say efficacy exaggerated and safety concerns ignored

Moderna's approval was based on findings from a Phase 3 study published in December 2023 of more than 35,000 adults across 22 countries that claimed the vaccine was 83.7% effective at preventing at least two symptoms of RSV, such as cough and fever, nearly four months post-vaccination.

Follow-up analysis by the FDA identified other cases and reduced the efficacy to 79%, the company said. That efficacy rate is in line with Arexvy, which currently dominates the RSV vaccine market, Reuters reported.

Cardiologist Dr. Peter McCullough wrote on his Substack that the efficacy claims were misleading.

"The absolute risk reduction for significant outcomes was far below 1%, meaning this product will not have a significant clinical impact," he wrote.

Absolute risk reduction refers to the actual difference in risk between the treated group versus the control group.

Relative risk reduction, which is how the company presented its trial data, is a proportional measure of how much a treatment reduced the risk of a bad outcome relative to the control group. It tends to lead to overestimations of how effective a treatment is.

Data presented in February also showed Moderna's shot has faster efficacy declines compared to the GSK and Pfizer shots, Reuters reported.

Moderna said there were no serious safety concerns identified in the trial. Adverse reactions reported in the clinical trial included injection-site pain (55.9%), fatigue (30.8%),

headache (26.7%), muscle pain (25.6%), joint pain (21.7%), underarm swelling or tenderness (15.2%) and chills (11.6%).

There were also two cases of acute pericarditis, which occurred after 42 days. The investigator considered those cases to be unrelated to the shot.

There were no reported cases of Guillain-Barré syndrome, which both Pfizer and GSK identified in their clinical trials and has subsequently proven to be "more common than expected," with the other RSV shots, according to the CDC.

However, McCullough said that for all mRNA shots, there are concerns about myocarditis, auto-immunity, genomic integration and oncogenicity. The rapid approval process does not allow the necessary time to identify a lot of these issues.

He wrote:

"Our great concern was that mRNA COVID-19 vaccines ushered in the context of an emergency would set a new precedent for more genetic vaccines that depart from all safety standards set forth previously by the US FDA. ...

"[The approval] was done without the full dossier of safety information required for a routine approval including 2-3 years of observation for standard vaccines, and at least

5 to 15 years of observation for genetic transfer technology."

Because the FDA's vaccine advisory committee didn't discuss the data, there was no publicly accessible discussion of the vaccine's efficacy and risk or space for public comment, which typically happens at such meetings.

The committee held meetings before the approval of both Arexvy and Abrysvo.

The FDA did not immediately respond to The Defender's inquiry about the lack of an advisory committee meeting or possible concerns with vaccine safety.

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.

The number of people who get RSV is unknown because the virus is rarely diagnosed unless one comes to a hospital and is tested.

Dr. Meryl Nass, an internist, told The Defender that among older people typically only those who are already ill or have very severe immune deficiency could benefit from an RSV vaccine.

"That benefit," she said, "must be weighed against all the harms, including those from the lipid nanoparticle as well as the mRNA and any

DNA plasmids or other extraneous production materials."

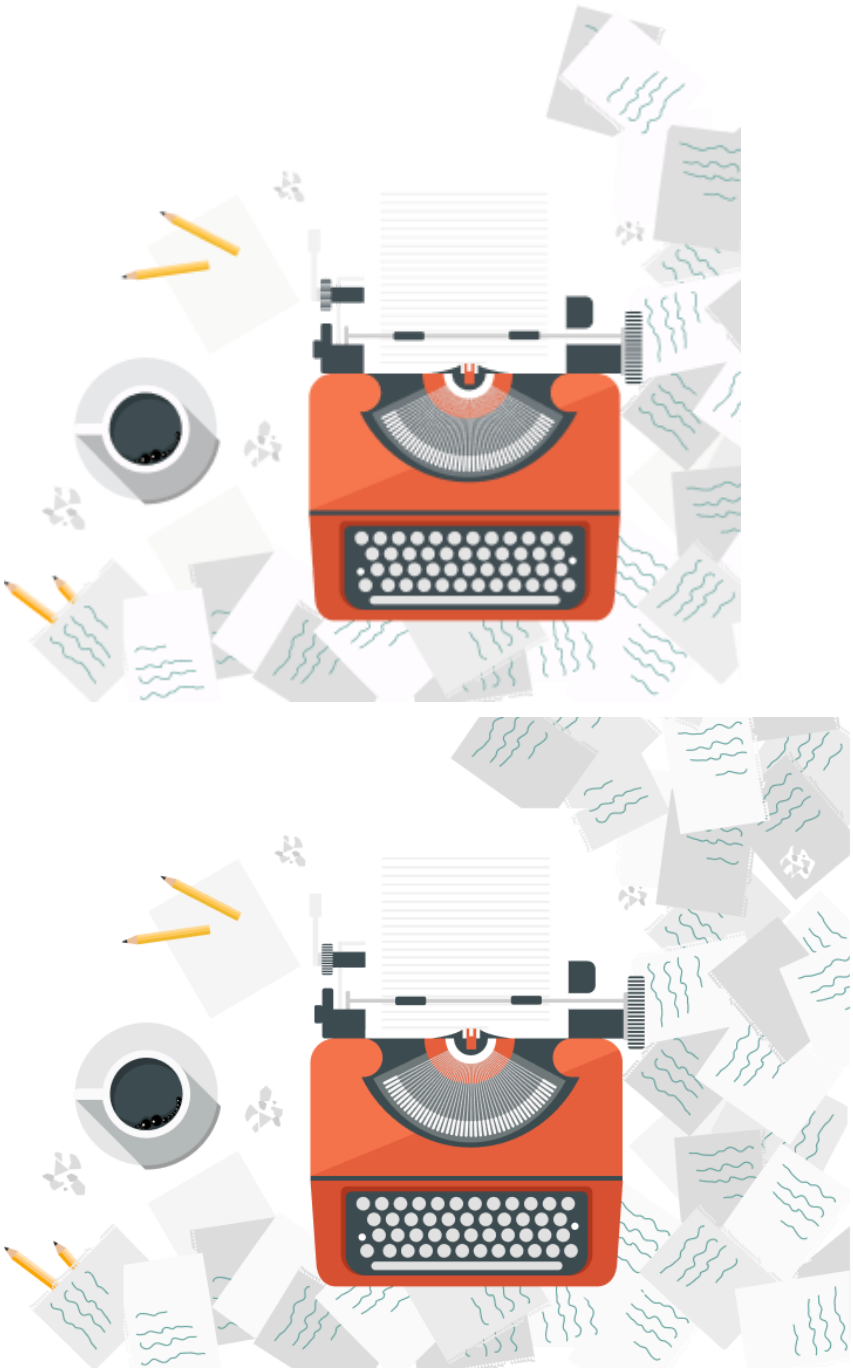
She said that mRNA vaccines are typically expensive and the amount of spending that would be necessary to save one life could take away from other essential health spending.

McCullough said, "Rare illnesses which are mild should not be the target for mass vaccination."

"In the case of respiratory syncytial virus, the illness is so mild and easily treatable with albuterol and budesonide nebulizers, it is hard to make the case for mass vaccination with a novel mRNA platform," he added.

Brian Hooker, Ph.D., chief scientific officer of Children's Health Defense, told The Defender that approval of this vaccine "is an absolute disaster in the making."

"The clinical trial was too short (average 112 days) to ascertain any long-term sequelae to the vaccine. Even with that, the rate of serious adverse events was 2.8% or 1 in 36 vaccine recipients," he said. "We can only expect the actual degree of damage will be much worse."



Moderna conducting testing on pregnant women and their infants

A search of the federal clinical trials database also revealed that Moderna is testing its mRNA RSV vaccine on pregnant women and their infants, despite concerns raised among this group with other RSV vaccines.

The ongoing Phase 2 trial in pregnant women will consist of 360 participants between 28 and 36 weeks of gestation at the time of vaccination. The trial is designed to determine dosing and potential adverse events associated with the vaccine.

GSK halted the development of its RSV vaccine for pregnant women when it found a safety signal for preterm births among vaccinated women. In that study, for every 54 infants born to women who received the vaccine, one additional preterm birth occurred.

Neonatal deaths — the death of an infant in the first 28 days of life — also were higher in the GSK vaccine group, occurring in 0.4% of the infants in the vaccine group (13 of 3,494) and 0.2% in the placebo group (3 of 1,739), which they also noted was not statistically significant.

The FDA approved Pfizer's Abrysvo for pregnant women in August 2023.

Pfizer's own clinical trial data for Abrysvo, which is very similar to GSK's vaccine, also 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.

The agency also labeled preterm birth as a potential risk associated with the vaccine.

Some members of the FDA's vaccine advisory committee said they had serious safety concerns based on the clinical trial data, and four members voted against approving the drug.

And a recent preprint study shows a statistically significant safety signal for preterm birth associated with Abrysvo.

Clinical trials for the COVID-19 mRNA vaccines did not include pregnant women.

However, subsequent research found the mRNA administered to lactating mothers spread systemically from the injection site to breast milk. Other post-marketing studies of the COVID-19 vaccine found mRNA in umbilical cord blood and in the placenta.

Moderna also has several other active clinical trials for the drug, including among people who are not at risk from RSV-related illness,

including children and adults, children ages 2-18, and healthy adults, among others.

It is also testing the drug among children ages 5-24 months.