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Written by **Veronika Kyrylenko** on June 19, 2026

FDA Panel Backs Moderna's Novel mRNA Flu Shot for Older Americans

Federal vaccine advisors gave Moderna's mRNA flu shot, called mFlusiva or mRNA 1010, a major boost Thursday.

The Food and Drug Administration's (FDA) expert panel, Vaccines and Related Biological Products Advisory Committee (VRBPAC), accepted Moderna's argument that mFlusiva could offer older Americans another layer of protection before the next flu season. In two unanimous votes, advisors concluded that the shot's benefits outweigh its risks for adults ages 50 to 64 and for those 65 and older.

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Supporters praised the mRNA platform as faster and more adaptable than older vaccine technologies.

But the vote did little to settle deeper concerns over Moderna's application. Critics pointed to modest efficacy, the use of a standard-dose comparator in the largest efficacy trial, and unresolved questions about long-term safety.

The vote does not approve the vaccine. The FDA still must make the final decision, which is expected in early August.

mRNA Flu Shot Advances

mFlusiva would become the first mRNA seasonal influenza vaccine in the United States if the FDA approves it.

The company seeks full approval for adults ages 50 to 64. It also seeks "accelerated" approval for adults 65 and older while it conducts more testing.

The Associated Press framed the vote as a step toward "a new kind of flu vaccine" made with the same "Nobel-prize winning" platform used in the Covid shots "that was key to ending" the pandemic. The outlet quoted Dr. Flor Munoz Rivas, an FDA advisor from Texas Children's Hospital, who said:

> Having this technology available puts us in a better position to be prepared for emerging strains in the future.

That is Moderna's core pitch. Flu viruses mutate quickly. Vaccine strains get selected months before the flu season begins. Manufacturers then produce the shots. If the virus drifts after that decision, the vaccine can miss the circulating strain.

Moderna says mRNA production could shorten that lag:

> Moderna's Dr. Rituparna Das told panelists that the company's ability to quickly manufacture mRNA vaccines that closely match the latest flu strains could prevent

> thousands of hospitalizations in older Americans.

FDA briefing materials made a similar point. The agency said mRNA manufacturing avoids egg-based production and may allow faster strain reformulation in response to antigenic drift or shift.

That argument carried weight with the panel.

What the Trial Showed

The key efficacy trial enrolled more than 40,000 adults ages 50 and older. It compared mFlusiva with a licensed standard-dose flu vaccine.

The result was statistically positive for Moderna. FDA reviewers said the shot reduced PCR-confirmed influenza-like illness by 26.6 percent relative to the standard-dose comparator. The confidence interval ranged from 16.7 percent to 35.4 percent.

In practical terms, 2.0 percent of people who received Moderna's shot developed protocol-defined influenza-like illness. The rate was 2.8 percent in the standard-dose comparator group.

The study also looked at a more-stringent modified CDC-defined influenza-like illness endpoint. There, mFlusiva produced a relative vaccine efficacy of 23.5 percent.

A separate exploratory analysis showed stronger results against cases requiring higher levels of care, including hospitalization, emergency room visits, or urgent care visits. FDA reviewers reported a relative vaccine efficacy of 47.9 percent for that endpoint.

Supporters treated those findings as evidence that the shot could provide a useful advantage.

FDA advisor Dr. Anna Durbin of Johns Hopkins University said the immune response data were "very compelling" and that "the vaccine looks very promising," according to AP.

Questionable Size of the Benefit

Critics saw a weaker case.

Dr. Jessica Rose, an immunologist and computational biologist, said Moderna's results do not show a major advance over existing flu vaccines. She wrote on X:

> Efficacy here is not transformative — it's better than standard-dose but unproven as clearly superior to existing enhanced flu vaccines in real-world use across multiple seasons.

That concern is reinforced by the trial design. Moderna's largest efficacy trial compared mFlusiva with a standard-dose flu vaccine. But that is not the type of flu shot CDC preferentially recommends for older Americans.

For adults 65 and older, CDC recommends high-dose, recombinant, or adjuvanted flu vaccines when available. And Moderna did not compare its new jab against those preferred senior vaccines.

Even FDA reviewers admitted that superiority over a standard-dose vaccine does not fully establish added value against the best available care for that age group.

Evidence Gaps

FDA reviewers also identified gaps in the data.

The studies relied largely on a single flu season. They excluded immunocompromised people. They also included few very frail older adults, even though those groups face high risks from influenza.

Rose maintained that those limitations affect the real-world meaning of the results. She cited "comparator choice, single-season data, and generalizability" as major problems.

The FDA briefing documents said the core data package had no major deficiencies. But they also made clear that some of the highest-risk populations remain under-studied.

Safety Concerns

FDA reviewers said the integrated safety data did not reveal major safety deficiencies. They also said Moderna's safety profile appeared acceptable for the intended population.

But the agency's own documents listed issues that require continued attention.

The studies followed participants for about six months. FDA reviewers noted numerical imbalances in several serious adverse events, including unspecified deaths, anemia cases, and urinary tract infections. The agency did not treat those imbalances as proven vaccine safety signals, and said no causal relationship had been established.

While the agency said that "no cases of myocarditis or pericarditis were identified within 42 days postvaccination," it still listed those conditions as events requiring monitoring, along with Guillain-Barre syndrome and other neurologic events.

A Children's Health Defense (CHD) report quotes both Rose and Dr. Angus Dalgleish, professor emeritus of oncology at City St. George's, University of London, who pointed to the known flaws of the current mRNA technology:

> "The case for mRNA gene therapies for any infectious disease can never be approved with current technology, given the totally unacceptable serious side effect risks," Dalgleish said.

Rose agreed:

> Since [mFlusiva is] based on the same flawed nucleoside-modified RNA-LNP platform as for the COVID shots, I anticipate exactly the same problems as for the COVID shots as per the millions of reported [adverse events] to pharmacovigilance databases.

She was also sharply critical of the effort to normalize mRNA technology for routine seasonal vaccination.

"There is a serious lack of transparency with regard to this technology touted as 'safe and effective'," Rose wrote. "It is neither."

More Reactions Than Conventional Shots

The early safety signals are not reassuring. Moderna's shot appeared to cause more short-term reactions than conventional flu shots.

Those reactions included injection site pain, fever, headache, fatigue, and body aches. In trial language, they are known as "solicited" adverse events, meaning reactions that participants were specifically asked to track after vaccination.

FDA reviewers said the reactions resolved within two days. They also described them as "typical" for mRNA vaccines.

Rose warned that the reaction profile should not be dismissed:

> Even the "acknowledged" reactions (solicited local reactions ~66% vs. ~30%, systemic symptoms notably higher (76% vs. 47% any solicited AE in some analyses)) are not a good indication for long-term profiles.

She argued that higher reactogenicity could matter most in frail seniors, who are also the group Moderna hopes to reach through the "accelerated" approval. That pathway allows the FDA to clear a product based partly on surrogate evidence, such as immune response data, before full clinical confirmation is available.

CHD also pointed to the vaccine's higher rate of these "solicited" adverse events:

> Several experts told The Defender that Moderna's mRNA-1010 vaccine poses risks. "Throughout the study, solicited adverse events are almost, and in some cases more than, double that of the comparator," [CHD senior research scientist Karl] Jablonowski said.

The VRBPAC did not see it as an issue.

What's Next

The FDA is expected to make its final decision on August 5. It generally follows the recommendations of its expert panels. Until then, Moderna's shot remains "investigational," meaning it has not been licensed for use outside clinical studies.

The panel's vote drew immediate criticism from the MAHA movement and other skeptics of federal vaccine policy.

"Why did this happen? Profits," posted Jeffrey Tucker of the Brownstone Institute.

His colleague Toby Rogers suggested the panel's endorsement was nothing short of "genocidal."

"Our regulatory agencies remain CAPTURED," wrote Nicolas Hulscher of the McCullough Foundation, describing high rates of the shot's adverse reactions. Steve Kirsch, a technology entrepreneur and prominent vaccine critic, noted that these reactions were serious enough to "impact people's daily lives."

The development is another reminder that the federal government has no constitutional authority to manage healthcare. As this magazine has long argued, that power must be returned to the states, local communities, and families currently forced to live with the consequences of harmful federal policies that are in major part shaped by the pharmaceutical lobby.