New American

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

FDA Reopens the Door to Moderna's mRNA Flu Shot

AP Images

The U.S. Food and Drug Administration (FDA) has reversed course on Moderna's seasonal influenza mRNA vaccine and agreed to review it for potential approval. The decision came just over a week after the agency refused to accept the company's original filing, stating the trial was not "adequate and well-controlled." Yet, following a swiftly arranged meeting between the FDA and Moderna, the agency reconsidered.

Moderna confirmed on Wednesday that regulators will now proceed with a formal review. Chief Executive Officer Stéphane Bancel welcomed the shift, stating:

> Pending FDA approval, we look forward to making our flu vaccine available later this year so that America's seniors have access to a new option to protect themselves against flu.

Politico reported on President Donald Trump's personal involvement in influencing the FDA's reversal. Make America Healthy Again (MAHA) activists, such as attorney Tom Renz, condemned the FDA's move as a "betrayal of MAHA, science, and common sense."

A Rejection That Did Not Last

Last Tuesday, the FDA's Center for Biologics Evaluation and Research (CBER) issued a Refusal-to-File (RTF) letter for Moderna's investigational influenza vaccine, mRNA-1010, intended for seniors. The agency declined to initiate review of the biologics license application (BLA).

Regulators cited concerns with Moderna's Phase 3 trial design. Specifically, they objected to the company's use of a licensed standard-dose seasonal influenza vaccine as the comparator. The FDA argued that this control "did not reflect the best-available standard of care" for older adults.

Notably, the refusal letter "did not identify any specific safety or efficacy concerns regarding mRNA-1010," stressed Moderna.

The company said that prior written communications with the agency accepted the use of a standard-dose comparator. In April 2024, during pre-Phase 3 consultations, regulators, in Moderna's telling, stated that such a comparator would be "acceptable." They also recommended using a vaccine preferentially endorsed by the Advisory Committee on Immunization Practices (ACIP) for participants over 65. The agency agreed that informed-consent disclosures could address this issue if Moderna proceeded with its original design.

The company completed its Phase 3 trial in September 2024, saying it met all pre-specified primary endpoints. Moderna later submitted additional analyses, including data comparing mRNA-1010 to a licensed high-dose influenza vaccine.

According to Moderna, regulators never indicated that refusal to review the application was likely.

What Really Happened With the Trials

Questions about Moderna's Phase 3 trial design have not been limited to regulators. Some observers have also raised concerns about the comparator used in the study.

Emily Kopp, editor-in-chief of Racket News, stressed how problematic Moderna's trial was:

> Moderna compared its mRNA flu vaccine against a flu vaccine that CDC doesn't recommend for seniors and only has ~14% efficacy in people >50. It could be as low as 0%. This is a trick drug companies use to inflate apparent efficacy, but it's unethical.

Dr. Jessica Rose agreed, posting that FDA's RTF was sound. She wrote with healthy sarcasm:

> I suppose Moderna don't realize that comparing nucleoside-modified mRNA-lipid nanoparticle encapsulated gene-based therapies and standard-dose influenza vaccines that rely on proteins derived from inactivated viruses is like comparing apples to idiots.

Kopp also stated that both the Biden and Trump administrations had previously advised the company to select a comparator that is recommended for older adults. According to her reporting, Moderna had evidence as early as four years ago that its mRNA flu candidate performed worse than the "standard-of-care" for seniors. Despite this, she said, the company continued development and investment in the product.

She further noted:

> Rates of fever and chills were higher after the mRNA flu vaccine than after flu cases in Moderna's clinical trial. Rates of serious side effects that keep you in bed were much higher for the mRNA flu vaccine.

Quoting Moderna's own presentation, Kopp wrote in another post:

> "So this vaccine gets us a decrease in cases (including non-serious ones) of **1/125,** but a **1/50** chance of a flu-like side effect so bad that you skip work, school, errands, etc." [Emphasis in original.]

"Feels like 2021. I'm getting nostalgic," she added.

The Review Moves Forward

Following its RTF letter, Moderna requested a so-called Type A meeting with the FDA. These meetings are typically granted after regulators decline to review an application as submitted and are meant to clarify deficiencies and outline a possible path forward.

During the meeting, informed the company,

> Moderna proposed a regulatory pathway based on age, seeking full approval for adults 50 to 64 years of age and accelerated approval for adults 65 and older, along with a post-

> marketing requirement to conduct an additional study in older adults.

And Moderna, apparently, was convincing:

> Following submission of the amended application, the FDA has accepted the biologics license application (BLA) for review and assigned a Prescription Drug User Fee Act (PDUFA) goal date of August 5, 2026.

If approved, the company said,

> mRNA-1010 would be available for U.S. adults 50 years of age and older, including adults 65 and older, for the 2026/2027 flu season.

Bancel described the agency's decision as constructive, saying:

> We appreciate the FDA's engagement in a constructive Type A meeting and its agreement to advance our application for review.

The company added that mRNA-1010 "has now been accepted for review in the United States, Europe, Canada and Australia." More submissions are coming this year.

The reports, however, suggest the FDA was pressured to soften its stance. Quoting two White House officials, *Politico* said that FDA Commissioner Dr. Marty Makary was summoned two days after Moderna disclosed the RTF letter, and "Trump expressed frustration … over the agency's handling of vaccine issues." A subsequent Type A meeting between Moderna and FDA officials was then scheduled unusually quickly, "[giving] them a public way to save face," per the outlet. The White House denied any pressure. Makary, in turn, described the RFT as a mere "part of a conversation" with the company.

Financial and Political Stakes

The commercial stakes are significant. The notorious Blackstone Group — the third largest equity firm and a globalist arm — has invested roughly $750 million in Moderna's flu vaccine development. Its chief executive, Stephen Schwarzman, is a major Republican donor and has contributed to Donald Trump's political campaigns.

Winning approval for an mRNA flu vaccine could reshape the company's financial outlook. Moderna's stock surged about six percent following news of the FDA's decision to review the amended filing. The company's valuation has fallen sharply since the vaccine mandates and propaganda campaign in 2021.

The MAHA, meanwhile, signaled that GOP political stock would crash should the FDA approve another poorly tested genetic injection. Dr. Toby Rogers of the Brownstone Institute, addressing White House Chief of Staff Susie Wiles, who is widely seen as a key power broker behind the administration, put it bluntly:

> If the Moderna mRNA flu shot is approved, the medical freedom movement will abandon the Republican Party in the midterm elections. That's not a threat, that's a promise.

Jeffrey Tucker, of the same organization, echoed the sentiment. He called the FDA's reversal a "betrayal

of the base" and "nothing more than a sop to Blackrock to save Moderna."

None of this, of course, would take place if the unconstitutional federal "public health" apparatus were dismantled and its colossal budget returned to the states to handle the matter. Instead, it has morphed into an enabler of Big Pharma's arguably genocidal greed.

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