PUBLICCITIZEN

1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

Testimony regarding the biologic drug application for mRNA-1010 (MFLUSIA) as a vaccine against influenza (flu)

Vaccine and Related Biological Products Advisory Committee

U.S. Food and Drug Administration

June 18, 2026

Michael T. Abrams, M.P.H., Ph.D.

I'm Dr. Michael Abrams, Senior Health Researcher at Public Citizen, a nonprofit consumer advocacy organization with over one million members. We have no financial conflicts of interest regarding today's topic.

The clinical data regarding mRNA-1010 (brand: mFlusiva) and the Food and Drug Administration's (FDA's) analysis of that data support the vaccine's traditional approval for individuals aged 50 to 64. The clinical data further support the limited accelerated approval of the vaccine for those 65 and older.[1] Safety and effectiveness both seem reasonable in the 50-to-64-year-old population, demonstrating that the mRNA vaccination can prevent serious flu-related morbidity (including medically attended illness) as well as or better than existing flu vaccines, with rare risk of serious adverse effects.

For those aged 65 and older the data are less certain, largely because the comparison treatment did not use Centers for Disease Control and Prevention (CDC)-recommended high-dose, adjuvanted or recombinant vaccine formulations for this older population. However, blood markers of the immune response (two forms) are reassuring that the mRNA-1010 vaccine is plausibly protective. Additionally, a large post-marketing study is planned to confirm the vaccine's safety and effectiveness over two seasons (2027-2028 and 2028-2029 seasons). Safety and effectiveness confirmation will be especially important in people older than 65 years and those who are immunocompromised or otherwise have pre-existing conditions. It is essential that the post-marketing study be

[1] Food and Drug Administration. FDA briefing document: BLA# 125869/0, Influenza Vaccine, mRNA (mFlusiva), Moderna TX, Inc. Vaccines and Related Biological Products Advisory Committee (CRBPAC). June 19, 2026. https://www.fda.gov/media/193130/download. Accessed June 17, 2026.

completed on the agreed-to schedule and that the findings are promptly published and reported to the public.

Public Citizen notes that the FDA's Vaccines and Related Biological Products Advisory Committee has now met twice within a one-month period. We urge the FDA to continue to frequently convene this committee as well as the many other expert advisory committees that the agency has insufficiently utilized since January 2025. [2] We also applaud the FDA for the scientific consideration of an important public health vaccine that uses mRNA technology.

Public Citizen, and many others outside the agency, remain deeply concerned that the FDA will reach decisions about important drugs, biologics and medical devices without public scrutiny and sufficient input from outside experts. We hope that today's advisory committee on this flu vaccine will be characteristic of the agency's approach going forward.

Thank you.

[2] Abrams, MT. Trump 2.0's Health Policy Playbook: Terminate or Overhaul Scientific Advisory Committees. March 18, 2026. https://www.citizen.org/article/trump-2-0s-health-policy-playbook-terminate-or-overhaul-scientific-advisory-committees/. Accessed June 17, 2026.