



2033 K Street, NW | Suite 450 | Washington, DC 20006

✉ info@agingresearch.org | www.agingresearch.org



June 18, 2026

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2026-N-4162 for Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments – Safety and Effectiveness of MFLUSIVA (Influenza Vaccine, mRNA) manufactured by Moderna TX Inc.

Thank you for the opportunity to submit public comments on the consideration of the MFLUSIVA (Influenza Vaccine, mRNA), for the prevention of influenza virus subtypes A and type B represented in the vaccine, for people ages 50 years and older.

While the undersigned organizations on this letter do not take a position on the merits of the application for the FDA approval of the mRNA vaccine for the prevention of influenza disease in people 50 years of age and older, we urge the Advisory Committee to consider the importance of the mRNA vaccines as well as the perspectives of older adults, family caregivers, long-term care and health care providers, and advocates as you discuss this Biological License Application (BLA).

Older Adults Are Disproportionately Impacted by Influenza

Older adults continue to experience a disproportionate burden of influenza-related hospitalization and mortality, underscoring the need for improved protection. Each year, adults ages 65 and older account for 50% to 70% of flu-related hospitalizations and 70% to 85% of seasonal flu-related deaths.¹ This burden increases with age due to age-related changes to the immune system—immunosenescence, and a higher occurrence of underlying chronic health conditions that can impact the immune system and increase the chances of complications.

Multiple Vaccine Options Support Individualized Approaches and Expand Access

Continued innovation should be welcomed as part of a broader public health strategy to reduce the burden of influenza and help protect those at greater risk. If approved, the MFLUSIVA vaccine would be the first mRNA-based influenza vaccine available to the public. According to a May 2026 study published in the *New England Journal of Medicine*, the mRNA flu vaccine reduced the risk of getting the flu by about 27% compared to standard shots during the 2024–2025 flu season in adults ages 50 and older, with the benefit consistent across older age groups.² Public health benefits when new technologies are rigorously evaluated and, when supported by evidence, are made available alongside existing preventive tools.

Currently, the CDC and the Advisory Committee on Immunization Practices (ACIP) preferentially recommend the use of higher dose flu vaccines (including high-dose inactivated and recombinant) or adjuvanted

¹ Centers for Disease Control and Prevention. Last updated 2024. Flu and People 65 Years and Older. <https://www.cdc.gov/flu/highrisk/65over.htm>.

² Isabel Leroux-Roels, M.D., Grace Huang, M.D., Murdo Ferguson, M.D., et. Al., "Efficacy and Safety of an mRNA Seasonal Influenza Vaccine in Adults," *N Engl J Med* 2026;394:1803–1813.

inactivated flu vaccine over standard-dose unadjuvanted flu vaccines for people 65 years and older.³ If this mRNA vaccine option were to be approved, it could provide value by supporting individualized approaches and giving clinicians and patients more choices over standard dose flu shots. This supports tailored medical decisions which can help to combat vaccine hesitancy and improve uptake.

Advancing mRNA Technology Preserves the Infrastructure Critical for Future Pandemics

More traditional egg-based and cell-based vaccine manufacturing typically requires a months-long production timeline, while mRNA technology can be manufactured and scaled much more rapidly. The long timeline of traditional vaccines can result in a lag between the manufactured vaccines and circulating influenza strains. The shortened timeline of mRNA vaccines could allow for strain composition to be decided later in the year, and vaccines to be manufactured closer to flu season.

And while seasonal influenza remains a significant public health threat, maintaining and advancing U.S.-based mRNA vaccine capabilities generally through routine public health programs helps preserve the scientific, manufacturing, and regulatory infrastructure that could be critical during a future pandemic.

Conclusion

Vaccines for older adults with heightened vulnerability to flu-related complications are welcome innovation. They help to support patient choice, expand access, and advance the public health infrastructure that combats seasonal flu and future pandemics.

For questions, please contact Lindsay Clarke, COO & SVP of Health Education at the Alliance for Aging Research, at llclarke@agingresearch.org. We thank the FDA and VRBPAC for consideration of our perspective and the opportunity to provide this input.

Sincerely,

AiArthritis
Alliance for Aging Research
America's Physician Groups
American Behcet's Disease Association
American Pharmacists Association
Caregiver Action Network
CaringKind, The Heart of Alzheimer's Caregiving
Diverse Elders Coalition (DEC)
Emergency Nurses Association
Families Fighting Flu
Global Coalition on Aging
IDSA
Lupus and Allied Diseases Association, Inc.
National Association of Nutrition and Aging Services Programs (NANASP)
National Black Nurses Association, Inc
National Foundation for Infectious Diseases
National Kidney Foundation
Nevada Chronic Care Collaborative
Post-Acute and Long-Term Care Medical Association
RetireSafe
Voices of Alzheimer's

³ Centers for Disease Control and Prevention. Last updated 2024. Flu and People 65 Years and Older.
<https://www.cdc.gov/flu/highrisk/65over.htm>.