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March 11, 2026

Division of Dockets Management
U.S. Food & Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Comments to the Docket No. FDA-2026-N-0826 for Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—United States (U.S.) 2026-2027 Influenza Vaccine Strain Composition

The [Alliance for Aging Research](http://www.agingresearch.org) (“Alliance”) thanks the FDA for scheduling the March 12 Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting and recognizing the importance of this annual convening to discuss and make recommendations on the strain composition of influenza virus vaccines for use in United States during the 2026-2027 influenza season. Advisory committees, including VRBPAC, play an important role in the regulatory ecosystem by providing an opportunity for independent scientific expertise and transparent public discussions of complex evidence. This open forum helps strengthen confidence that regulatory decisions are informed by rigorous analysis and diverse expert perspectives, and we encourage the Agency to continue leveraging these venues to support transparent scientific dialogue going forward.

While we are encouraged by this VRBPAC meeting, we note our concern about the 7 reported vacancies on the committee, including the chairperson’s role. We urge the FDA to fill these vacancies in accordance with the committee charter, which requires that VRBPAC “shall consist of at least fifteen voting members including the Chair.”

Both the VRBPAC and the FDA have consistently recognized the CDC’s findings that influenza is a significant cause of severe illness, hospitalization, and death, and its burden is known to be highest in older adults, children younger than 2, and individuals with underlying health conditions.¹ While flu seasons vary in severity, during most seasons, people 65 years and older bear the greatest burden of severe flu disease. In recent years, for example, it’s estimated that between 70 percent and 85 percent of seasonal flu-related deaths have occurred in people 65 years and older, and between 50 percent and 70 percent of seasonal flu-related hospitalizations have occurred among people in this age group.²

¹ People at Increased Risk for Flu Complications, CDC website at <https://www.cdc.gov/flu/highrisk/index.htm>.

² Flu and People 65 Years and Older, CDC website at <https://www.cdc.gov/flu/highrisk/65over.htm>.

Within the important context outlined above, we urge the VRBPAC and the FDA to:

1. Provide manufacturers with a timely recommendation regarding the 2026-2027 updated strain for influenza vaccines for use in the United States, so that production can begin without delay and vaccines are available ahead of the upcoming respiratory season;
2. Reaffirm the agency's commitment to not subject currently approved or authorized influenza vaccines—or annual strain updates to those vaccines—to new requirements for randomized clinical trials using inert placebos; and
3. Recognize that influenza poses a year-round risk in long-term care settings and ensure that vaccine availability and coverage policies reflect that reality.

I. Provide Manufacturers with a Timely Strain Recommendation for the 2026-2027 Influenza Season

FDA has played a critical leadership role in identifying and recommending virus strains for annual updates to influenza vaccines. In consultation with the CDC, the WHO, the VRBPAC, and others, FDA has established a highly functional timeline and process. The predictability of this timeline for strain selection is crucial to ensuring vaccine availability in advance of the upcoming season.

Strain selection must occur with sufficient lead time to allow manufacturers to produce, test, and distribute adequate vaccine supplies. Delays in strain selection cascade into delays in production and distribution and ultimately result in reduced vaccination rates at exactly the moment when protection is most needed. We urge FDA to faithfully follow this well-established, transparent, highly functional process and provide manufacturers with a timely recommendation for the 2026-2027 strain.

II. Reaffirm That Approved and Authorized Influenza Vaccines and Annual Strain Updates Will Not Be Subject to New Randomized Placebo-Controlled Trial Requirements

Vaccines remain the most effective way for an individual to reduce the risk of serious illness, hospitalization, and death from influenza. FDA has reviewed and affirmed the safety and efficacy of influenza vaccines available in the United States through its well-established regulatory review processes. The influenza vaccines authorized and approved by FDA have undergone rigorous evaluation, and their benefit-risk profile across all approved age groups is not in dispute. Additionally, we are pleased to see industry pursue and adopt innovations, including newer technologies, with the goals to help develop more precise protection and improved strain matching over time.

The World Health Organization guides the ethical use of placebos in vaccine trials.³ The WHO states that a placebo-controlled vaccine trial is acceptable when no effective vaccine is available, and the new vaccine is intended to benefit the population being studied. However, the WHO guidelines state that using placebos is considered unacceptable when there is already an effective and safe vaccine accessible in the public health system of the country where the trial is planned. In such cases, it would be unethical to withhold the existing vaccine from participants if not receiving it would pose a significant risk to their health.

Flu vaccines have been in use in the United States for decades. Science supporting their safety and efficacy is not in question. Requiring manufacturers to conduct inert placebo-controlled trials for annual strain updates to long-authorized vaccines would not generate meaningful new safety or efficacy data but would

³ “Expert Consultation on the Use of Placebos in Vaccine Trials,” World Health Organization (WHO) 2013

simply delay availability, increase costs, and expose trial participants to preventable harm. Strain updates do not change vaccine platforms; they update the antigens to match circulating strains, precisely as they have done for decades under FDA's existing review process.

However, we write today with serious concerns about reports that the U.S. Department of Health and Human Services may seek to require all vaccines—including influenza vaccines and their annual strain updates—to be evaluated in randomized clinical trials using inert placebos, such as saline shots.⁴ The Alliance strongly opposes the application of any such requirement to influenza vaccines, and we urge VRBPAC and the FDA to reaffirm publicly that no such requirement will be imposed.

The potential introduction of new FDA clinical data requirements for influenza vaccines could create significant operational challenges for manufacturers preparing vaccines for the 2026-2027 U.S. influenza season, particularly if such requirements were introduced in spring 2026 without sufficient advance visibility or opportunity for stakeholder input. In January 2026, the FDA Center for Biologics Evaluation and Research (CBER) released its [2026 Guidance Agenda](#), which states that the Agency plans to release “Guidance for Industry” entitled “Clinical Data Needed to Support the Licensure of Seasonal Inactivated Influenza Vaccines.” The title does not specify whether the guidance will address initial biologics license applications, annual strain updates, or both, and the scope and timeline has not yet been defined publicly.

Additional requirements should be considered in the context of the extensive clinical trial experience and decades of safety data supporting currently approved influenza vaccines. The current seasonal influenza vaccine development is uniquely time-sensitive and operationally complex. Manufacturers begin producing vaccine components at risk in February to ensure timely shipping of product in July ahead of the fall respiratory season in the Northern Hemisphere. The compressed timeline is essential to ensuring vaccine availability before peak influenza circulation.

Any attempt to conduct traditional large, randomized trials using a given strain vaccine would likely result in delays so significant as to render the updated vaccine irrelevant to the circulating strains it is meant to address. Instead, large real-world evidence datasets accumulated over decades confirm the soundness of an approach for influenza vaccines that relies on strain-matched annual updates reviewed through FDA's existing, well-functioning process.

Given the operational realities of the influenza production cycle, any revisions to the framework should:

- Be developed transparently, with appropriate opportunity for stakeholder engagement and public comment;
- Clearly delineate requirements applicable to initial licensure versus annual strain updates;
- Account for the extensive clinical and safety evidence accumulated over decades of seasonal influenza use;
- Provide sufficient implementation lead time to avoid disruption to upcoming influenza seasons.

Additionally, to-date the FDA has approved or authorized influenza vaccines that provide different options for patients and providers depending on an individual's age, health status, and preferences. CDC and ACIP preferentially recommend the use of higher dose flu vaccines ([high-dose inactivated](#) and [recombinant](#)) or [adjuvanted inactivated flu vaccine](#) over [standard-dose unadjuvanted flu vaccines](#) for people 65 years and

⁴ RFK Jr. to require placebo-controlled studies for new vaccines, May 1, 2025, <https://www.npr.org/sections/shots-healthnews/2025/05/01/nx-s1-5383172/rfk-jr-placebo-vaccine-testing-studies>

older. This recommendation is based on a review of available studies which suggests that, in this age group, these vaccines are potentially more effective than standard dose unadjuvanted flu vaccines. If one of these vaccines is not available at the time of administration, people in this age group should get a standard-dose unadjuvanted inactivated flu vaccine instead.

We urge FDA to continue to honor patient and provider choices, and to promote uptake by facilitating the continued availability of all currently authorized options. Beyond issues of choice, supply chain stability is a practical and public health imperative. Relying on multiple vaccine manufacturers decreases the risk of a potential vaccine shortage, should there be a future supply chain disruption.

III. Ensure That Coverage and Availability Policies Reflect Influenza’s Year-Round Risk in Long-Term Care Settings

While influenza has historically been characterized as a seasonal illness, the reality for residents of nursing homes and other long-term care facilities is more complex. In congregate care settings, influenza activity does not neatly confine itself to a traditional seasonal window. For the many Americans living in nursing homes, the majority of whom have multiple underlying conditions placing them at the highest risk of severe illness, the window of vulnerability is not seasonal. It is continuous.

The COVID-19 pandemic has underscored how quickly respiratory viruses can spread through long-term care settings and how devastating the consequences can be for medically fragile residents. The same dynamics apply to influenza. Policies governing influenza vaccine availability, production timelines, and coverage must account for this year-round risk, not merely the traditional October-March window.

The severity of recent influenza seasons further underscores the urgency of these concerns. Both the 2024-2025 and 2025-2026 seasons have been classified as “high severity” for children, with 293 pediatric reported for the 2024-2025 season. More concerning, the influenza vaccination rates among children continue to trend in the wrong direction, and there has been no clear, consistent communication from CDC or federal public health authorities reinforcing the importance of vaccination. The Alliance urges FDA and VRBPAC to consider this context as they make decisions affecting vaccine availability and access.

In addition, coverage policies, reimbursement structures, and vaccine availability timelines that treat influenza as a disease confined to a discrete window do not reflect the reality faced by nursing home residents and the healthcare workers who care for them. We urge FDA to ensure that its review and authorization timelines support the earliest possible vaccine availability, and we encourage the agency to engage with CMS and other partners to ensure that coverage policies are aligned with the year-round vulnerability of long-term care populations.

Conclusion

Influenza vaccines are among the most rigorously evaluated and consistently effective public health tools available. The annual strain update process is a scientific and logistical achievement that has protected Americans for decades. Any disruption to the predictability and integrity of that process, whether through delays in strain selection, new clinical trial requirements that are not scientifically justified, or policies that fail to account for year-round risk in vulnerable settings, will result in preventable illness, hospitalization, and death.

The Alliance also urges the FDA to ensure that any additions to influenza vaccine packaging labels are supported by robust, comprehensive evidence before implementation. We are concerned that recent decisions to include warning related to febrile seizures associated with influenza vaccines were made without data spanning more than two influenza seasons. This evidentiary basis is insufficient to justify labeling changes that could generate unwarranted concern and confusion among patients across the lifespan, as well as their providers. Any research used to support vaccine labeling decisions should be made readily and publicly available so that patients, clinicians, and the broader scientific community can evaluate the underlying evidence.

We appreciate the opportunity to provide this input and thank you for your attention to these comments.

Sincerely,

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