

May 14, 2025

[Submitted electronically via Federal eRulemaking Portal: Regulations.gov]

Vaccines and Related Biological Products Advisory Committee Center for Biologics Evaluation and Research, Food and Drug Administration 10903 New Hampshire Ave., Bldg. 71 Silver Spring, MD 20993-0002

Re: Docket No. FDA-2025-N-1146 Meeting of the Vaccines and Related Biological Products Advisory Committee (May 22, 2025)

Dear Vaccines and Related Biological Products Advisory Committee:

The American Pharmacists Association (APhA) is the largest association in the United States, advancing the entire pharmacy profession and representing our nation's over 340,000 pharmacists, 30,000 student pharmacists, and more than 400,000 pharmacy technicians. We are writing to provide input related to the Food and Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) upcoming meeting and request an opportunity to comment.

Pharmacists and those under pharmacists' supervision administer the majority of voluntary influenza and other vaccines to adult patients in our nation, including Medicare and Medicaid beneficiaries, as well as those who receive care from the Veterans Affairs and through our U.S. military, Indian Health, immigration, and prison facilities worldwide. According to the available 2024 – 2025 season influenza data, over sixty percent of the influenza vaccines were administered in pharmacies.¹ During the 2023 – 2024 respiratory season, ninety-six percent of RSV vaccines were administered in pharmacies.² As of April 12, 2025, almost ninety percent of COVID-19 vaccines have been administered in pharmacies.³ As one of the most accessible immunizing professionals, pharmacists' ability to immunize is salient in the health care system, providing the best defense possible against vaccine-preventable diseases.

Most patients, particularly in rural and underserved areas, typically come to pharmacists first when they have a health question or concern. Often, pharmacists are the only health care providers for miles. Because pharmacies are located in nearly every rural community and inner-city neighborhood, pharmacists and pharmacy personnel provide unparalleled access to care within

¹ Influenza vaccinations administered in pharmacies and physician medical offices*, adults, United States. (2025, April 9). FluVaxView. https://www.cdc.gov/fluvaxview/dashboard/adult-vaccinations-administered.html

² 2023-24 Respiratory Syncytial Virus (RSV) Vaccinations Administered in Pharmacies and Physician Medical Offices (IQVIA), Adults 60 years and older. (2024, September 25). RSVVaxView. https://www.cdc.gov/rsvvaxview/dashboard/2023-24-adult-vaccinations-administered.html

³ COVID-19 vaccinations administered in pharmacies and medical offices*, adults 18 years and older, United States. (2025, May 7). COVIDVaxView. https://www.cdc.gov/covidvaxview/weekly-dashboard/vaccinations-administered-pharmacies-medical.html

the health care system. It is imperative that VRBPAC continues to convene subject matter experts without conflicts of interest who critically apply scientific methods to evaluate evidence. APhA commends the Administration for planning to convene in May 2025 and encourages maintaining a regular cadence of meetings.

APhA appreciates the advancement of influenza vaccine strain selection and manufacturing for the 2025 – 2026 season but is concerned about the previous cancellation of the March VRBPAC meeting and the lack of scheduled meetings for the remainder of 2025. We look forward to the May 2025 convening to select the strains for the 2025 – 2026 COVID-19 vaccines. It will be imperative to select strains at this meeting to assure time for manufacturing and delivery of updated COVID-19 vaccines to protect the most vulnerable and immunocompromised patients prior to the fall respiratory virus season. Pharmacists stand ready to vaccinate patients across their lifespan, but need timely receipt of and access to safe and effective vaccines to do so. VRBPAC meetings provide the public with an overview of the latest data on the safety and effectiveness of all recommended vaccines and new vaccines in development. VRBPAC, with its independent experts, provides transparency in the vaccination recommendation process to health care professionals and the public. We hope and strongly recommend that future VRBPAC meetings be held publicly and regularly scheduled. Vaccines are our best defense against vaccine-preventable diseases, and we must ensure that the recommended vaccines we receive and administer continue to be safe.

Thank you for the opportunity to comment on the upcoming VRBPAC meeting. We look forward to continued collaboration.

Most sincerely,

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