



June 22, 2025

The Honorable Martin A. Makary, M.D., M.P.H.  
Commissioner of Food and Drugs  
Food and Drug Administration (FDA)  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

**RE: An Evidence-Based Approach to COVID-19**

Dear Commissioner Makary,

APhA supports the use of sound, scientifically reviewed evidence when approving vaccines.

Before a health care provider can administer the first dose of any vaccine in the United States, several agencies, groups, and committees must have reviewed it for safety and effectiveness. This process consists of multiple steps, on purpose, as researchers, scientists, and health care providers want patients to trust that the vaccine is safe and protects them from future disease.

After the FDA has approved a vaccine, the Advisory Committee on Immunization Practices (ACIP) can consider it for its recommendation to be included in CDC's U.S. adult and childhood immunization schedules.<sup>1</sup> ACIP has up to 18 voting members who are experts in fields and studies related to vaccines and appointed by the Secretary of the U.S. Department of Health and Human Services (HHS).<sup>2</sup> At least one member represents consumers.<sup>3</sup> The HHS Secretary removed all 17 current members and announced that he would replace them with all new members on June 9, 2025.<sup>4</sup> APhA strongly urges that the voting membership of ACIP be comprised of scientists, researchers, and clinicians—including pharmacists—who possess the clinical and scientific acumen to provide evidence-based recommendations for vaccines, in a non-partisan manner. There are also thirty-one non-voting members representing health professional organizations who provide comments on ACIP's recommendations.<sup>5</sup> Each member of ACIP is required to disclose any potential or perceived conflicts of interest prior to being selected and during their tenure, which are publicly

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<sup>1</sup> Role of the Advisory Committee on Immunization Practices in CDC's Vaccine Recommendations, CDC (Sept. 17, 2024). Available at: <https://www.cdc.gov/acip/about/role-in-vaccine-recommendations.html>.

<sup>2</sup> Apply for ACIP Membership, CDC (Dec. 20, 2024). Available at: <https://www.cdc.gov/acip/apply-for-membership/index.html>.

<sup>3</sup> *Id.* Available at: <https://www.cdc.gov/acip/apply-for-membership/index.html>.

<sup>4</sup> HHS Takes Bold Step to Restore Public Trust in Vaccines by Reconstituting ACIP, U.S. Department of Health and Human Services (June 9, 2025). Available at: <https://www.hhs.gov/press-room/hhs-restore-public-trust-vaccines-acip.html>.

<sup>5</sup> Role of the Advisory Committee on Immunization Practices in CDC's Vaccine Recommendations, CDC (Sept. 17, 2024). Available at: <https://www.cdc.gov/acip/about/role-in-vaccine-recommendations.html>.

available.<sup>6</sup> ACIP's review considers multiple factors, including the safety and effectiveness of the vaccine for the specific age group, the seriousness of the vaccine-preventable disease, and the vaccine's public health benefit, before making a recommendation to the CDC director for the use of the vaccine.<sup>7</sup> The CDC Director can then approve the recommendation, making the vaccine's use a part of official health guidance.<sup>8</sup> These recommendations are then instrumental in determining which vaccines health care providers, especially pharmacists, should give their patients. In a majority of states, pharmacists', student pharmacists', and pharmacy technicians' authority to administer vaccines is linked only to those recommended by ACIP for specific age groups, indications, or patients' past medical history.<sup>9</sup> Most vaccines, including 63% of influenza and 96% of respiratory syncytial virus (RSV) vaccines, are administered in pharmacies by pharmacists, pharmacy technicians, and student pharmacists.<sup>10</sup> Additional states reference ACIP, CDC, FDA, or other federal agencies in state law regarding pharmacists', student pharmacists', and pharmacy technicians' authority, educational requirements, protocols, or processes when administering vaccines.<sup>11</sup> **Any changes in ACIP recommendations could impact insurance coverage of these vaccinations as well as the authority of pharmacist and pharmacy teams to administer vaccines, who according to federal data, provide the majority of adult vaccinations each year saving millions of lives and billions of dollars to our health care system.**

The vaccine approval process outlined in “An Evidence-Based Approach to COVID-19 Vaccination,” departs from this well-established process, which guarantees multiple levels of scientific review.<sup>12</sup> The publication outlines a new COVID-19 vaccine-specific regulatory framework that bypasses many checkpoints that promote scientific review in the vaccine approval process. These checkpoints are what instill confidence and trust in the American people to get vaccines approved by FDA. This publication, in combination with the Secretary of HHS's use of a social media platform to change current vaccine recommendations, sets a precedent that one person or a small group of people can circumvent this entire process. Such behavior devalues and discredits the weight and work of the researchers, scientists, health care providers, and other experts who review and evaluate data during the approval process and in creating the recommendations, and will lead to less transparency and greater distrust of FDA-approved vaccines.

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<sup>6</sup> Conflicts of Interest Disclosures of ACIP Members, CDC (Mar. 7, 2025). Available at: <https://www.cdc.gov/acip/disclosures/by-member.html> (noting that a list of conflicts of interest disclosures can be found on the cited website).

<sup>7</sup> Role of the Advisory Committee on Immunization Practices in CDC's Vaccine Recommendations, CDC (Sept. 17, 2024). Available at: <https://www.cdc.gov/acip/about/role-in-vaccine-recommendations.html>.

<sup>8</sup> *How Vaccines Are Developed and Approved for Use*, CDC (Aug. 10, 2024). Available at: <https://www.cdc.gov/vaccines/basics/how-developed-approved.html>.

<sup>9</sup> AL, AZ, CA, GA, HI, IN, IA, KY, LA, ME, MI, MN, MT, NH, NM, NY, NC, ND, OK, OR, PA, RI, SC, UT, VT, WI, WY.

<sup>10</sup> *Influenza Vaccinations Administered in Pharmacies and Physician Medical Offices, Adults, United States*, CDC (May 7, 2025). Available at: <https://www.cdc.gov/fluview/dashboard/adult-vaccinations-administered.html>. See also *Respiratory Syncytial Virus (RSV) Vaccinations Administered in Pharmacies and Physician Medical Offices\*, Adults, United States*, CDC (May 7, 2025). Available at: <https://www.cdc.gov/rsvview/dashboard/adult-vaccinations-administered.html>.

<sup>11</sup> AK, CO, CT, DC, FL, IL, MD, MO, NJ, NV, OH, TN, TX, VA, WV.

<sup>12</sup> Vinay Prasad & Martin A. Makary, *An Evidence-Based Approach to Covid-19 Vaccination*, *The New England Journal of Medicine* (May 20, 2025). Available at: <https://www.nejm.org/doi/full/10.1056/NEJMs2506929>.

Recent changes to the COVID-19 vaccine recommendations from HHS include removing recommendations for people who are pregnant to receive the COVID-19 vaccine. Noting that pregnancy is a high-risk condition, and people who are pregnant should be recommended to receive the COVID-19 vaccine, APhA is withholding its endorsement of the ACIP Adult Immunization Schedule issued on May 28, 2025. APhA is the only pharmacy representative among several professional organizations that reviews and evaluates the ACIP Adult Immunization Schedule annually. APhA's decision was proposed by a group of APhA members who are immunization subject matter experts and approved by the APhA Board of Trustees. Research shows that people who are pregnant or were recently pregnant are at a greater risk of becoming very sick from COVID-19 compared with those who are not; are more likely to require hospitalization, intensive care, or the use of a ventilator or special equipment to breathe if they do become ill from COVID-19; and are at greater risk of complications that can affect pregnancy and the baby.<sup>13</sup> Studies have shown that COVID-19 vaccination during pregnancy is both safe and effective.<sup>14</sup> Furthermore, the vaccine is not associated with any fertility issues for women or men.<sup>15</sup> APhA would reconsider its endorsement upon the schedule being discussed and recommended by ACIP.

The vaccine approval process provides for scientific review, transparency, and order. Recent studies show that “across all vaccines for adults in-scope, a large majority of the administration took place at the pharmacy level compared to a non-pharmacy medical setting.”<sup>16</sup> In fact, the majority of COVID-19 and shingles vaccines throughout the year and flu vaccines during respiratory season were administered in pharmacies in 2022, highlighting the integral relationships between patients and their pharmacists when taking measures to prevent certain diseases via immunization.<sup>17</sup> Pharmacists trust the vaccine approval process because of the system of checks and balances that ensure the recommended vaccines are safe and effective, and patients trust their pharmacists because they keep them healthy. Bypassing any step in this process breaks this trust and will lead to more vaccine hesitancy, less transparency, and a greater risk of the spread of vaccine-preventable

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<sup>13</sup> Koji Matsuo, et al., *Severe Maternal Morbidity and Mortality of Pregnant Patients With COVID-19 Infection During the Early Pandemic Period in the US*, JAMA Network Open (2023). Available at: <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2803485>. See also Ke Xu, et al., *The Impact of COVID-19 Infections on Pregnancy Outcomes in Women*, 24 BMC Pregnancy and Childbirth 562 (2024). Available at: <https://bmcpregnancychildbirth.biomedcentral.com/articles/10.1186/s12884-024-06767-7>. See also Shang-Ming Zhou, et al., *COVID-19 and Pregnancy: A Comprehensive Study of Comorbidities and Outcomes*, 24 BMC Public Health 3157 (2024). Available at: <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-024-20416-w>. See also Jean Y. Ko, et al., *Adverse Pregnancy Outcomes, Maternal Complications, and Severe Illness Among US Delivery Hospitalizations With and Without a Coronavirus Disease 2019 (COVID-19) Diagnosis*, 73 Clinical Infectious Diseases 15 (2021). Available at: [https://academic.oup.com/cid/article/73/Supplement\\_1/S24/6274300](https://academic.oup.com/cid/article/73/Supplement_1/S24/6274300).

<sup>14</sup> Katherine E. Fleming-Dutra, et al., *Safety and Effectiveness of Maternal COVID-19 Vaccines Among Pregnant People and Infants*, 50 Obstetrics and Gynecology Clinics of North America 279 (2023). Available at: <https://www.sciencedirect.com/science/article/pii/S0889854523000372?via%3Dihub>. See also Smriti Prasad, et al., *Systemic Review and Meta-Analysis of the Effectiveness and Perinatal Outcomes of COVID-19 Vaccination in Pregnancy*, 13 Nature Communications 2414 (2022). Available at: <https://www.nature.com/articles/s41467-022-30052-w>.

<sup>15</sup> D. Zace, et al., *The Impact of COVID-19 Vaccines on Fertility - A Systemic Review and Meta-Analysis*, 40 Vaccine 6023 (2022). Available at: <https://www.sciencedirect.com/science/article/pii/S0264410X22011185>. See also *COVID-19 Vaccination for Women Who Are Pregnant or Breastfeeding*, CDC (Sept. 10, 2024). Available at: <https://www.cdc.gov/covid/vaccines/pregnant-or-breastfeeding.html>.

<sup>16</sup> *Trends in Vaccine Administration in the United States*, IQVIA (Jan. 13, 2023). Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/trends-in-vaccine-administration-in-the-united-states>.

<sup>17</sup> *Id.* Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/trends-in-vaccine-administration-in-the-united-states>.

diseases. APhA urges HHS to maintain the established vaccine approval process that reassures Americans that vaccines have gone through rigorous and sound scientific testing and review with intentional checks and balances.

For more than 25 years, APhA has been a liaison representative to ACIP. APhA has proudly brought our members' expertise from across the country to the table and ensured that the voice of the nation's top and most trusted provider of vaccines. APhA recognizes there is risk and choice when it comes to any medication, including vaccines. Pharmacists consistently work with patients to balance their individual health conditions and risks with choice of therapy, whether it be medications or immunizations. As such, pharmacists are best positioned to have these conversations with their patients. We recognize that the risk and choice of medications and vaccines must be founded on rigorous, peer-reviewed science and driven by empirical evidence.

No pharmacists are serving as voting members of ACIP despite being the largest adult vaccine providers. While APhA has supported the applications of pharmacists for such an appointment, none of our candidates have ever been selected by the Secretary. As HHS understands, while ACIP's recommendations help guide the use of vaccines to control diseases, these recommendations are only adopted as official CDC policy once approved by the CDC Director, who is nominated by the President and confirmed by the U.S. Senate. **We are hopeful that you will advise the HHS Secretary to select a pharmacist as a voting member of ACIP based on practical vaccination experience and medication expertise. APhA would be delighted to work with you to identify a well-qualified pharmacist to serve in this capacity and has submitted pharmacist candidates to the HHS Secretary.**

Thank you for considering ensuring America's trusted medication experts take on a larger role at the ACIP table. Many rural communities have no access to health care except for their local pharmacist, and APhA offers its assistance to support your efforts to improve our nation's health. APhA can help your administration lower health care costs and support local small businesses and our patients. Please contact Michael Baxter on my staff at [mbaxter@aphanet.org](mailto:mbaxter@aphanet.org) to arrange a meeting with me to discuss these recommendations.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Hogue", is written over a light gray rectangular background.

Michael Hogue, PharmD, FAPhA, FNAP  
APhA Executive Vice President and CEO

CC: The Honorable Robert F. Kennedy, Jr., Secretary, HHS