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Re: Docket No. CDC-2025-0024 for Request for Comments for "Advisory Committee on Immunization Practices (ACIP) June 25-26, 2025"

Dear ACIP Members,

Thank you for the opportunity to submit a comment for the June 25-26, 2025, meeting of the CDC's Advisory Committee on Immunization Practices (ACIP).

The <u>Alliance for Aging Research</u> (the "Alliance") is the leading nonprofit organization dedicated to changing the narrative to achieve healthy aging and equitable access to care. For the past nine years, the Alliance has led the <u>Our Best Shot</u> educational campaign, which encourages vaccine confidence, aims to increase vaccination rates, and arms older adults with reliable information about vaccines. The Alliance is also a co-convener of <u>the Champions for Vaccine Education, Equity & Progress (CVEEP)</u>, a trusted source of information and a leading voice in discussions on vaccines and treatments for infectious respiratory disease.

Vaccines represent one of our most effective tools in preventing disease and improving quality of life, especially for older adults. Recognizing their importance, we respectfully submit the following recommendations for your consideration:

#### 1) Restore ACIP Votes on COVID-19 Vaccine Recommendations

Data from the CDC's COVID-19 Vaccines Workgroup presented at the April 15-16, 2025, ACIP meeting continues to show that COVID-19 remains a significant cause of severe illness, hospitalization, and death across the lifespan in the United States. The risk of COVID-19-related death is known to be highest in older adults, and the CDC reported more than 36,000 deaths among people aged 65 and older between September 2023 and

August 2024. Among children under the age of 18, there were an estimated 152 deaths during that same time—53 of which in babies under a year old. Additionally, 300,000 children in the U.S. have long COVID.<sup>2</sup>

We appreciate the CDC's continued commitment to COVID-19 vaccine evaluation with the ACIP, particularly considering effectiveness data presented at the April meeting indicating vaccine protection comparable to influenza vaccines among high-risk groups. Like the flu, the percentage of American adults considered at higher-risk for severe illness from the COVID-19 virus is high (74%), which supports a broader age-based recommendation.<sup>3</sup> The issue was tabled and announced that it would be deliberated and decided on at the June ACIP meeting.

However, on May 27, Health and Human Services Secretary Robert F. Kennedy Jr. pre-empted the June ACIP meeting, when he announced on X that COVID-19 vaccines would be immediately removed from the ACIP's recommended schedule for healthy pregnant people and children. There was no explanation given for why this decision was made without the ACIP's input and recommendation vote.

In addition, the decision was inconsistent with the FDA's new COVID-19 vaccine framework, which was published in a commentary piece on May 20, authored by FDA Commissioner Dr. Martin Makary and FDA Center for Biologics Evaluation and Research Director, Dr. Vinay Prasad. In the piece, Drs. Makary and Prasad state, "the FDA anticipates that it will be able to make favorable benefit—risk findings for adults over the age of 65 years and for *all persons above the age of 6 months with one or more risk factors that put them at high risk for severe Covid-19 outcomes, as described by the CDC* [emphasis added]." The CDC lists "pregnancy and recent pregnancy" in its list of 22 underlying-condition categories linked to higher risk of severe COVID-19 illness. Higher risk is defined by the CDC as "an underlying medical condition or risk factor that has a published meta-analysis or systematic review or underwent the CDC systematic review process. The meta-analysis or systematic review demonstrates a conclusive increase in risk for at least one severe COVID-19 outcome."

In addition, on June 9, the American Pharmacists Association (APhA) put out a press release stating that

"APhA's stance is that pregnancy is a high-risk condition; therefore, people who are pregnant should be recommended to receive the COVID-19 vaccine. The May 2025 updates to the COVID-19 vaccine recommendations do not appear to be based on the scientific evidence provided over the past few years. Considering this recent change, APhA has decided to withhold endorsing the current ACIP Adult Immunization Schedule issued on May 28, 2025. This decision was proposed by a group of APhA members who are immunization subject matter experts and approved by the APhA Board of Trustees.

APhA is the only pharmacy representative among several professional organizations that reviews and evaluates the ACIP Adult Immunization Schedule annually.

The removal of a recommendation for "healthy" individuals under the age of 65 is also concerning. There are many reasons to still get immunized even if you are "healthy," such as being a family caregiver for someone in a higher risk category. According to recent reports, it is estimated that between 53 million to 105.6 million U.S. adults provide unpaid caregiving for family and friends. Of these, an estimated 5.4 million children and

<sup>&</sup>lt;sup>1</sup> Lakshmi Panagiotakopoulos, MD, MPH, Use of 2025–2026 COVID-19 Vaccines: Work Group Considerations, April 2025 ACIP Meeting at <a href="https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID508.pdf">https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID508.pdf</a>.

<sup>&</sup>lt;sup>2</sup> Ford ND, Vahratian A, Pratt CQ, Yousaf AR, Gregory CO, Saydah S. Long COVID Prevalence and Associated Activity Limitation in US Children. JAMA Pediatr. Published online February 03, 2025.

<sup>&</sup>lt;sup>3</sup> Lakshmi, slide 14 at https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID-508.pdf.

adolescents in the U.S. are direct caregivers for family members. The decision will eliminate personal freedom and choice for parents and their families and will make it much harder for parents to get their children vaccinated and for pregnant people to get the shots, as insurance companies will likely no longer pay for them.

We encourage ACIP to restore its votes on COVID-19 vaccine recommendations (as stated in the Federal Register, Vol. 90, No. 109, Monday, June 9, 2025, Notice). We also urge the CDC to finalize its recommendations and coordinate closely with manufacturers to avoid any delays on production and availability of COVID-19 vaccines for the Fall and Winter respiratory season. Timely recommendations are critical for ensuring vaccine availability and optimal protection during the next respiratory season.

# 2) The CDC Should Finalize ACIP's April Vote to Lower the Risk-Based Recommendation for RSV Vaccines to Adults Aged 50-59

RSV continues to present significant risks to older adults, contributing to 42,000 hospitalizations a year in adults ages 50-64 in the U.S., as well as increased mortality rates. Additionally, over 13 million U.S. adults aged 50-59 have at least one diagnosed medical condition that increases their risk for severe complications of RSV.<sup>4</sup> Lowering the risk-based recommended vaccination age provides earlier and more widespread protection, reducing disease burden and associated healthcare costs.

The Alliance was pleased that ACIP voted to lower the risk-based recommendation for RSV vaccines to adults aged 50 and older at its April 2025 meeting, and we urge the CDC to finalize this recommendation.

# 3) Remove the ACIP Vote on Proposed Recommendations Regarding Thimerosal-Containing Influenza Vaccine

Thimerosal is a mercury-containing organic compound. Since the 1930s, thimerosal has been widely used as a preservative in several biological and drug products, including many vaccines, to prevent the growth of harmful microbes inadvertently introduced into the vaccine during use.<sup>5</sup>

The FDA considers the <u>United States Pharmacopeia (USP)</u> standards when evaluating the safety and effectiveness data for vaccines containing thimerosal as a preservative. The USP is "an independent, scientific nonprofit organization focused on building trust in the supply of safe, quality medicines." According to the FDA, "At concentrations found in vaccines, thimerosal meets the requirements for a preservative as set forth by the United States Pharmacopeia (USP); that is, it kills the specified challenge organisms and can prevent the growth of the challenge fungi. Thimerosal in concentrations of 0.001% (1 part in 100,000) to 0.01% (1 part in 10,000) has been shown to be effective in clearing a broad spectrum of pathogens. A vaccine containing 0.01% thimerosal as a preservative contains 50 micrograms of thimerosal per 0.5 mL dose or approximately 25 micrograms of mercury per 0.5 mL dose. For comparison, this is roughly the same amount of elemental mercury contained in a 3 ounce can of tuna fish."6

We are very concerned that a discussion on thimerosal will further threaten overall vaccine confidence.

<sup>&</sup>lt;sup>4</sup> Horn EK, Singer D, Booth A, Saiontz-Martinez C, Berger A. Disparities in risk factors for severe respiratory syncytial virus disease among adults in the United States. Poster presented at: National Foundation for Infectious Disease Annual Conference on Vaccinology Research. May 8-10, 2024, Online.

US Food and Drug Administration. Thimerosal and Vaccines: https://www.fda.gov/vaccines-blood-biologics/safety-availabilitybiologics/thimerosal-and-vaccines.

<sup>&</sup>lt;sup>6</sup> Ibid.

The FDA states that thimerosal has been the subject of numerous studies (see Bibliography-Notable Studies and Assessments Supporting the Safe Use of Thimerosal in Vaccines) and has a long record of safe and effective use preventing bacterial and fungal contamination of vaccines, with no ill effects established other than minor local reactions at the site of injection.

According to the FDA, the documented antimicrobial properties of thimerosal contribute to the safe use of vaccines in multi-dose vials, and the ability to package certain vaccines, such as those for seasonal and pandemic influenza, in multi-dose vials helps facilitate immunization campaigns in the United States and globally that save lives. However, the use of thimerosal as a preservative in U.S. FDA-licensed vaccines has significantly declined due to reformulation and development of vaccines presented in single-dose containers.<sup>7</sup>

# We strongly urge the CDC to remove the ACIP vote on "Thimerosal containing influenza vaccine recommendations."

### 4) Reinstate the ACIP vote on influenza vaccines for this year's strain

At the April 2025 ACIP meeting, it was announced that the votes on influenza vaccines for this year's strain would be taken at the June meeting. The <u>Federal Register</u>, Vol. 90, No. 109, Monday, June 9, 2025, Notice also mentions that there would be a vote on influenza vaccines.

We also encourage the committee to offer preferential recommendations on higher-dose and enhanced flu vaccines for older adults and specific high-risk groups. While any flu vaccine is better than none, the data clearly show that higher-dose options are more effective for these groups.

A vote on removing the restriction of FluMist Self or Caregiver Administration for individuals with asthma and wheezing was on the agenda for February's ACIP meeting but was not included in the April or June meeting agendas. For individuals with asthma, receiving an annual influenza vaccine is highly recommended for reducing exacerbated asthma symptoms from influenza and death. Recent studies showed that FluMist did not exacerbate wheezing or asthma symptoms any more than the inactive influenza vaccine that is already approved for these groups. In one study, 151 children with asthma, aged 5 to 17, received a flu shot or nasal mist vaccine for two flu seasons. Rates of wheezing and asthma attacks were the same for both groups 42 days after they got their vaccines, the study findings showed.<sup>8</sup>

We ask the committee to include this vote to remove restrictions for FluMist for individuals with asthma or wheezing in the next ACIP meeting to expand access to these individuals.

Additionally, FluMist Self or Caregiver Administration provides an important new option for receiving a safe and effective seasonal influenza vaccine, with greater flexibility and accessibility for individuals and caregivers. The inclusion of FluMist as a self or caregiver-administered vaccine expands vaccination choices and helps overcome barriers that may limit vaccine uptake.

<sup>&</sup>lt;sup>7</sup> US Food and Drug Administration. Thimerosal and Vaccines. <a href="https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/thimerosal-and-vaccines#table">https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/thimerosal-and-vaccines#table</a>.

<sup>&</sup>lt;sup>8</sup> Sokolow AG, Stallings AP, Kercsmar C, Harrington T, Jimenez-Truque N, Zhu Y, Sokolow K, Moody MA, Schlaudecker EP, Walter EB, Staat MA, Broder KR, Creech CB. Safety of Live Attenuated Influenza Vaccine in Children With Asthma. Pediatrics. 2022 Apr 1;149(4):e2021055432. doi: 10.1542/peds.2021-055432. Erratum in: Pediatrics. 2022 Aug 1;150(2):e2022058263. doi: 10.1542/peds.2022-058263. PMID: 35342923; PMCID: PMC11235090.

## 5) Restore Votes on Vaccines for Children (VFC) Vaccines

The Federal Register, Vol. 90, No. 109, from Monday, June 9, 2025, states, "Vaccines for Children (VFC) votes are scheduled for COVID-19 vaccines, HPV vaccine, influenza vaccines, and RSV vaccines." However, the current ACIP meeting agenda only includes one VFC vote on RSV vaccines. We urge the ACIP to restore its originally planned VFC votes for COVID-19 vaccines, HPV vaccine, and influenza—along with the scheduled vote on RSV vaccines.

The Vaccines for Children (VFC) Program is a federally funded program established in 1994 to provide free vaccines to eligible children in the United States. It was created in response to a measles outbreak in 1989-1991, which highlighted disparities in vaccination rates among low-income children. The VFC program ensures that all children have access to recommended vaccinations, regardless of their ability to pay.

The VFC Program Automatically covers vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) and approved by the CDC, which includes all vaccines for children ages 18 years and younger. The VFC Program-provided vaccines currently protect against 19 different diseases, which are estimated to prevent 472 million illnesses and 29.8 million hospitalizations.<sup>9</sup>

If ACIP does not vote on Vaccines for Children program resolutions for COVID-19 vaccines, HPV vaccine, and influenza—along with the scheduled vote on RSV vaccines—at this meeting, there will be no guarantee of free COVID-19, HPV, flu, and RSV vaccines offered to children who need them this fall.

The VFC program is crucial for ensuring comprehensive immunization coverage across the life course, starting in childhood. The Alliance advocates for healthy aging across the lifecycle, which includes access to immunization, and urges ACIP to prioritize timely access to all relevant and essential vaccines.

#### 6) Provide a Measles Outbreak and Vaccination Update and Exercise Continued Vigilance

We request an update on the ongoing measles outbreak and an update on vaccination uptake. According to the CDC, as of June 19, 2025, a total of 1,214 confirmed measles cases were reported by 36 jurisdictions: Alaska, Arkansas, Arizona, California, Colorado, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Missouri, Montana, Nebraska, New Jersey, New Mexico, New York City, New York State, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Virginia, and Washington. <sup>10</sup> Of the 1,214 confirmed cases, 29% (350 cases) were in children under 5 years of age.

Measles can be severe. Of the cases confirmed in 2025 so far, 12% (146) have been hospitalized—of those hospitalized, 49% (72 of 146) were children under 5 years of age.

We are very concerned about what the undefined topic is regarding MMR vaccine in children under 5 years of age. What could ACIP possibly discuss on this topic, other than that CDC needs to significantly focus vaccination confidence and uptake efforts for families with children in this age group? The CDC states that the measles vaccine prevents infection 97% of the time, dramatically reduces the risk of complications, and there are no documented cases of a healthy, fully vaccinated person dying from the virus. Prior to the introduction of the measles vaccine in 1963, the virus used to kill about 500 Americans and disable about 1,000 every year.

<sup>&</sup>lt;sup>9</sup> Vaccines for Children (VFC) Program: Information for Parents: https://www.cdc.gov/vaccines-for-children/vfc-information-forparents/index.html.

10 Measles Cases and Outbreaks, https://www.cdc.gov/measles/data-research/index.html.

The ACIP should urge the CDC to continue to prioritize comprehensive measles case reporting, vaccination confidence and uptake. Measles is the most contagious infectious disease in the United States. Complications can be especially dangerous in children and older populations, causing serious conditions such as pneumonia and encephalitis, and even leading to death. Maintaining high vaccination rates in babies and younger cohorts is essential to preventing outbreaks and protecting vulnerable older adults. Additionally, the data should be explored to better understand if older adults should be receiving measles boosters to protect against outbreaks of a disease that was previously considered eradicated in the U.S.

## 7) Maintain ACIP's Scientific Integrity and Independence

It is overreach for the FDA to engage in population-based recommendations for the clinical use of vaccines. For more than 50 years, the Advisory Committee on Immunization Practices (ACIP) has been the public-facing, transparent committee established by Congress and convened by the Centers for Disease Control and Prevention (CDC) that has provided expert perspectives and advice on the use of vaccines in the U.S. population. ACIP recommendations of FDA-approved or authorized COVID-19 vaccines are fundamental to ensuring that vaccines are not only available but also covered under both public and private insurance programs, including the Vaccines for Children Program (VFC) which covers more than half of the children in the United States.

The ACIP has consistently been a trusted advisory body that closely followed administrative rules regarding conflicts of interest, rotating terms, and transparency. We hope the new appointees continue to uphold these values and prioritize science rather than appearing the Secretary. Restoring public trust in vaccines is not achieved by undermining science but is *earned* through transparency and evidence-based policy that protects public health.

ACIP recommendations of FDA-approved or authorized vaccines are fundamental to ensuring that vaccines are not only available but also covered under both public and private insurance programs.

We have appended our official statement on Secretary Kennedy's removal of all previous ACIP members to this comment letter.

Thank you again for the opportunity to provide written comments for ACIP's June 25-26 meeting. The Alliance looks forward to continued collaboration with ACIP to advance effective vaccination strategies.

Sincerely,

Katrin Werner-Perez Director of Health Programs Alliance for Aging Research

Katrin Werner-Derez

Susan Peschin, MHS President & CEO Alliance for Aging Research

Susan Peschin