December 4, 2025

Kirk Milhoan, MD, PhD Chair, Advisory Committee on Immunization Practices (ACIP)

Minah Zadeh, PhD, MPH
Executive Secretary, ACIP
Supervisory Program Specialist
Centers for Disease Control & Prevention

Re: Docket No. CDC-2025-0783 for Request for Comments for "Advisory Committee on Immunization Practices (ACIP) December 4 - 5, 2025, Meeting"

Dear Advisory Committee on Immunization Practices (ACIP) Members,

As mostly non-pediatric organizations representing public health, older adults, patients, family caregivers, consumers and healthcare workers, we support everyone having access to every vaccine they need, regardless of their age. In the United States alone, routine childhood vaccinations for children born between 1994 and 2023 are projected to prevent about 1.13 million deaths, and hundreds of millions of illnesses and hospitalizations. Put simply, childhood vaccines make healthy adults.

We are very concerned about the December 4-5 ACIP meeting agenda items that appear to question the longstanding evidence-based and well-established pediatric and adolescent vaccine schedules. To align with the Administration's commitment to "Restoring Gold Standard Science," we urge the CDC and Committee to abide by the ACIP Charter and Workgroup Guidance, including its Evidence to Recommendations framework, and the Grading of Recommendations Assessment, Development and Evaluation (GRADE).

The ultimate decision of whether to get a vaccine should be limited to patients, families, and their clinicians. The recommendations approved by this committee not only translate to clinical practice but also have implications for coverage and reimbursement, which significantly impact access. Recognizing the critical importance of this meeting, we respectfully submit the following recommendations:

## Maintain the Current Recommendations for Hepatitis B, Including the Birth Dose

Clinical and public health data have consistently shown that <u>universal administration of</u> the hepatitis B vaccine within the first 24 hours of life is the most effective strategy to prevent early childhood infections. Since the U.S. adopted the universal hepatitis B birth dose recommendation 35 years ago as the standard of care, it has led to a 99% reduction in cases of acute hepatitis B in kids under age 19.

The U.S. has already tried, and failed, using a targeted risk-based vaccination strategy to prevent perinatal and early childhood hepatitis B transmission. Prior to the 1991 schedule change, nearly 20,000 babies and children were infected annually in the U.S., and most infections went undiagnosed until later in life, frequently when liver cancer or significant liver damage had already developed. The <u>risk of long-term complications</u> from hepatitis B infections is extremely high in infants, with up to 90% of babies infected in their first year developing a chronic hepatitis B infection.

The CDC currently recommends that clinicians should screen all pregnant patients for HBsAg during each pregnancy, preferably in the first trimester, regardless of vaccination status, chronic infection, and testing history. As many as two-thirds of people in the U.S. don't know that they have hepatitis B, and this includes pregnant women despite the screening. This is because early screening doesn't detect infections acquired later in the pregnancy. Infants can also be exposed to hepatitis B after birth by living with or being cared for by someone with an infection.

We strongly urge ACIP to keep votes consistent across both the standard and Vaccines for Children (VFC) Program recommendations. The VFC program serves over 50% of children in the United States and ensures equitable access to vaccines, regardless of a family's financial situation. Removing or limiting access to vaccines through the VFC program disproportionately harms low-income and underserved populations and sews inconsistency into vaccine coverage, thereby punishing those who are already vulnerable.

Additionally, we remind ACIP that AHIP—the national trade association representing the health insurance industry—announced in September 2025 that health plans will continue to cover all ACIP-recommended immunizations that were recommended as of September 1, 2025, with no cost-sharing for patients through the end of 2026. We are grateful to AHIP members for their meaningful commitment to evidence-based vaccine coverage.

It goes against gold standard science to consider reversing decades of public health progress, and to needlessly change a recommendation that provides a safe, effective, and cost-effective prevention strategy for a virus that has no cure.

**Recommendation:** Maintain the universal birth dose and schedule for hepatitis B and preserve provider and parental choice in both the standard and Vaccines for Children (VFC) program recommendations.

## Recognize that Adjuvants are Safe and Critical for Some Vaccines

Adjuvants play a critical role in enhancing the immune response to vaccines, particularly for older adults. Aluminum-based adjuvants have long been established as safe and are

essential for improving vaccine efficacy by boosting the body's immune reaction to the antigen. A comprehensive study on aluminum adjuvants in the July 15, 2025, issue of the *Annals of Internal Medicine* among 1.2 million children over 20 years found *no association* between aluminum exposure from vaccines and the development of 50 chronic conditions, including autism.

Aluminum is abundant in many everyday items, including tap water, baby formula, cereal, flour, vegetables, cheese, and much more—and in amounts significantly greater than a childhood vaccine. The body naturally clears the aluminum ingested. When injected through a vaccine, the aluminum adjuvants remain localized and are efficiently cleared by the body, therefore not accumulating to harmful levels.

Addressing safety concerns about vaccine ingredients should rely on scientific evidence. The ACIP's role is to evaluate vaccines' safety and effectiveness comprehensively, relying on rigorous scientific data and expert consensus. Discussions on adjuvant safety should continue to be informed by the broader scientific community and regulatory bodies dedicated to vaccine safety monitoring.

**Recommendation:** Defer to the broader scientific community regarding the safety of vaccine adjuvants and other ingredients, and to refrain from recommendation votes on these topics.

## Conclusion

The timing of each vaccine in the schedule is based on clinical studies and real-world evidence on safety. This schedule has proven to work, and we are concerned about the Committee's willingness to re-open established recommendations based on assumptions. Narrowing or removing recommendations will restrict access and create barriers to patient and provider choice. We urge the Committee to maintain the current vaccine schedule.

Thank you for the opportunity to provide these comments. We look forward to collaborating with ACIP to advance science-based, effective vaccination strategies.

Sincerely,

**AAPACN** 

Academy of Managed Care Pharmacy

(AMCP)

Academy of Medicine of Cleveland &

Northern Ohio (AMCNO)

AFT: Education, Healthcare, Public

Services AiArthritis

Aimed Alliance

Allergy & Asthma Network

Alliance for Aging Research

Alliance for Women's Health and

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**Immunology** 

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American Association of Psychiatric

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Caregiver Action Network

CaringKind

Chronic Care Policy Alliance Chrohn's & Colitis Foundation

**Emergency Nurses Association** 

Families Fighting Flu Generations United

Gerontological Advanced Practice Nurses

Association

Gerontological Society of America

Global Coalition on Aging

Global Healthy Living Foundation

HealthHIV

HealthyWomen

Illinois Public Health Association

Immunize Colorado

Infectious Diseases Society of America

Justice in Aging

**NAPCRG** 

National Association of Nurse

Practitioners in Women's Health

National Association of Nutrition and

Aging Services Programs (NANASP)

National Black Nurses Association, Inc.

National Committee to Preserve Social

Security and Medicare

National Consumers League

National Health Law Program

National Hispanic Council on Aging

National Hispanic Health Foundation

National Kidney Foundation

**Neuropathy Action Foundation** 

Nevada Chronic Care Collaborative

New Orleans Health Department

Nurses Who Vaccinate

Partnership to Fight Chronic Disease

(PFCD)

Partnership to Fight Infectious Diseases

(PFID)

Pediatric Nurse Practitioner House Calls

RetireSafe

Society of Teachers of Family Medicine

The Task Force for Global Health

Vasculitis Foundation

Village to Village Network

Voices for Vaccines