September 19, 2025

Martin Kulldorff, 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-2025-0454 for Request for Comments for "Advisory Committee on Immunization Practices (ACIP) September 18-19, 2025, Meeting"

Dear Advisory Committee on Immunization Practices (ACIP) Members,

As organizations representing public health, patients, family caregivers, and healthcare professionals, we have a clear stake in the availability of vaccines. Vaccines represent one of our most effective tools in preventing disease and improving quality of life, throughout the lifespan. The proceedings and recommendations of the CDC's ACIP have a huge impact on trust and confidence in vaccines, and in Americans' ability to access those life-saving vaccines. Recognizing the critical importance of this meeting, we respectfully submit the following recommendations:

## Uphold the Process and Gold Standard of the ACIP

For more than 50 years, the ACIP has been a trusted source of evidence-based vaccine recommendations that guide healthcare professionals, patients, families, and payers. The process by which this committee reviews and makes recommendations on the use of vaccines has historically been based on the best data and evidence available. As new science emerges, the committee has also been diligent in making informed and updated recommendations that are in the best interest of the American people. Upholding this critical process and standards are essential to avoid creating confusion among patients and healthcare professionals and exacerbating distrust in government health agencies.

**Recommendation:** 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) approach.

## Vote to Recommend the Full Schedule of Vaccines and Ensure Access and Patient Choice

The ACIP recommendations not only guide patients and providers but are also linked to what people must pay out-of-pocket to get those vaccines. Many insurers, as well as <u>Medicare Part D plans</u> and the <u>Vaccines for Children Program</u>, are required to cover the vaccines recommended by ACIP. However, if these recommendations are withdrawn or revised, insurers may no longer be required to pay for these shots, leaving people with uncertainty and large bills to pay.

Because of this lack of clear guidance, <u>pharmacies in certain states are now requiring prescriptions for COVID-19 vaccines or aren't even offering them</u>. This means that fewer people can get the vaccines, and

those that do qualify face significant new hurdles. There is no doubt that vaccine rates are going to drop precipitously, and we will all feel the devastating effects.

**Recommendation:** The ACIP must act decisively to approve the full schedule of vaccines without limiting choice and creating barriers to access. We urge the committee to allow access to the people who need and want these vaccines.

## Vote to Recommend the COVID-19 Vaccines for All Americans 6 Months and Older

COVID-19 has become endemic and remains a significant public health threat. The latest estimates from the September 2024 to September 2025 in the United States indicate that COVID-19 infections were responsible for an estimated 3.2-4.6 million outpatient visits, 360,000-520,000 hospitalizations, and 42,000-60,000 deaths. This burden of COVID-19 deaths is shouldered disproportionately by Americans aged 65 and older and other high-risk groups.

In addition to older age, there are more than 20 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." Such conditions include asthma, cerebrovascular disease, chronic kidney disease, cystic fibrosis, diabetes mellitus (type 1 and type 2), and certain types of cancer, chronic lung diseases, and chronic liver diseases, among many others—as well as pregnancy. In addition, the CDC identifies being overweight or obese as a strong, independent risk factor for severe infection and death due to COVID-19. This is especially significant for the U.S., where nearly 3 in 4 adults are now considered overweight or have obesity. In total, an estimated 74% of adults in the U.S. have at least one condition that puts them at higher risk of severe illness from COVID-19.

The FDA's May 2025 COVID-19 Vaccine Framework and its August 2025 decision to modify labeling indications for COVID-19 vaccines were consistent—both indicate the vaccines for adults 65 and older, and those six months and over who have at least one high-risk condition. However, the COVID-19 vaccine recommendations announced by HHS officials on May 27 via social media, introduced new restrictions on pregnant women that were inconsistent with the framework and labels.

This mass confusion has raised concerns that are currently playing out. In particular, the uncertainty about how to define high-risk for COVID-19 is creating a <u>patchwork system of coverage policies across states</u>. Physicians <u>have also raised questions about liability</u> for off-label prescribing.

For those who are otherwise "healthy," but still at risk of falling ill and having serious complications, they may be left without options. Many of these individuals are family or professional caregivers that spend time with high-risk individuals and do not want to expose them to the virus. By narrowing who can get these vaccines and making it increasingly hard to obtain vaccines for those that qualify, we are leaving large holes in our public health defenses.

**Recommendation:** We urge the committee to clear up the confusion and recommend the COVID-19 vaccines for all Americans ages 6 months and up—restoring choice for those that want to protect themselves from illness, transmission, and long-term complications. Such a recommendation promotes personal choice and puts clinical decision-making back in the hands of healthcare professionals, patients, and their family caregivers. It would also better facilitate reasonable coverage and reimbursement than the current risk-based scheme.

Importantly, AHIP—the national trade association representing the health insurance industry—<u>announced early this week</u> that, "Health plans will continue to cover all ACIP-recommended immunizations that were recommended as of September 1, 2025, including updated formulations of the COVID-19 and influenza vaccines, 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.

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) AiArthritis Aimed Alliance

Allergy & Asthma Network Alliance for Aging Research

Alliance for Women's Health and Prevention

Alzheimer's Los Angeles

American Association for Geriatric Psychiatry American Association of Colleges of Nursing American Association of Nurse Practitioners American Behcet's Disease Association (ABDA)

American College of Nurse-Midwives

American Geriatrics Society American Kidney Fund

American Pharmacists Association American Public Health Association

American Society for Clinical Laboratory Science

American Society on Aging

Association for Professionals in Infection Control

and Epidemiology

Association of Black Cardiologists

Asthma and Allergy Foundation of America

Autism Society of America Autoimmune Association

California Chronic Care Coalition

Cancer Nation (formerly National Coalition for

Cancer Survivorship)
Caregiver Action Network

CaringKind, The Heart of Alzheimer's Caregiving

Chronic Care Policy Alliance Crohn's & Colitis Foundation Dia de la Mujer Latina Inc Diverse Elders Coalition Emergency Nurses Association

Generations United

Gerontological Advanced Practice Nurses

Association (GAPNA)

Gerontological Society of America

Global Coalition on Aging

Global Healthy Living Foundation

HealthHIV HealthyWomen

Hydrocephalus Association Illinois Public Health Association Immune Deficiency Foundation

Immunize Colorado

Infectious Diseases Society of America

LeadingAge

Lupus and Allied Diseases Association, Inc.

National Alliance for Caregiving

National Association of Nutrition and Aging

Services Programs (NANASP)

National Association of Pediatric Nurse

Practitioners

National Association of School Nurses National Black Nurses Association, Inc

National Consumers League

National Foundation for Infectious Diseases

National Hispanic Council on Aging National Hispanic Health Foundation Nevada Chronic Care Collaborative

Nurses Who Vaccinate

Partnership to Fight Chronic Disease Partnership to Fight Infectious Disease Pediatric Nurse Practitioner House Calls Post-Acute and Long-Term Care Medical

Association

Premier Integrated Medical Associates

Prevent Blindness

RetireSafe Sepsis Alliance

Southeast Asia Resource Action Center (SEARAC)

Support Services of Virginia, Inc.

The diaTribe Foundation

The National Association of Nurse Practitioners

in Women's Health

The Task Force for Global Health

Vaccinate Your Family Voices for Vaccines Voices of Alzheimers