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June 20, 2025

Stephanie Thomas

Committee Management Specialist

Advisory Committee on Immunization Practices

National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

1600 Clifton Road NE, Mailstop H24-8

Atlanta, GA 30329

Attn: Docket No. CDC-2025-0024

Dear Ms. Thomas:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of 67,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety and well-being of all infants, children, adolescents, and young adults, I welcome the opportunity to submit comments for the June 25-26, 2025, Advisory Committee on Immunization Practices (ACIP) meeting.

AAP advocates for policies and programs that help ensure all children are vaccinated and that all communities are protected from devastating vaccine-preventable diseases. Pediatricians are a key source of accurate, evidence-based information about vaccines for parents, and AAP leads efforts to counter vaccine misinformation, increase vaccine confidence, and emphasize the overall safety and efficacy of vaccinations.

Pediatricians have relied on the ACIP's evidence-based recommendations to guide clinical practice, support vaccine confidence, and ensure equitable access to immunization services. We therefore submit this comment letter to express our deep concern regarding recent developments that we believe significantly undermine the integrity of the ACIP and the public's trust in the nation's immunization program:

1. The May 27, 2025, unilateral decision to alter COVID-19 vaccine recommendations for healthy children and pregnant individuals;
2. The June 9, 2025, termination of all seventeen ACIP members and their replacement with unvetted and unqualified appointees and the dismissal of ACIP liaison members and workgroups;
3. The anticipated votes on the inclusion of maternal and pediatric RSV vaccines in the routine immunization schedule, as well as a subsequent vote to determine whether pediatric RSV vaccines will be added to the federally funded Vaccines for Children (VFC) program; and
4. The anticipated votes on "Thimerosal containing influenza vaccine recommendations."

The ACIP has long been regarded as a model of scientific rigor, transparency, and independence. Beyond their clinical significance, ACIP recommendations are embedded in a wide array of federal and state legal frameworks. Under Section 2713 of the Public Health Service Act, as amended by the Affordable Care Act, insurers are required to cover ACIP-recommended vaccines without cost-sharing. ACIP recommendations are routinely referenced in statutes at the state level, such as school entry immunization requirements and pharmacist scope of practice. In addition, in accordance with Section 1928 of the Social Security Act, ACIP recommendations comprise the list of immunizations for administration to children and adolescents eligible to receive vaccines through the VFC program. As such, changes to ACIP recommendations have

far-reaching implications for insurance coverage, provider reimbursement, and patient access, as well as for the legal and operational infrastructure that supports immunization delivery.

The change in recommendations for COVID-19 vaccination in children and pregnant individuals is especially troubling as these populations remain at risk for severe outcomes from COVID-19. The May 27 decision, which was announced in a video message by Secretary of Health and Human Services (HHS), Robert F. Kennedy, Jr., deviates from the traditional process that relies on ACIP deliberation and recommendation, and we urge the CDC and ACIP to release the full evidentiary basis for this change prior to making any formal decisions, including any risk-benefit analyses, modeling data, and stakeholder input that informed the decision.

The unprecedented dismissal of all seventeen ACIP members on June 9, 2025, and their replacement with individuals whose qualifications and independence have not been thoroughly vetted is also troubling. We are also concerned about the removal of liaison members and the cancellation of various workgroup meetings. The strength of ACIP lies in its multidisciplinary expertise, its insulation from political influence, and its adherence to a transparent, deliberative process. The wholesale replacement of its membership with individuals lacking demonstrated experience in immunology, epidemiology, pediatrics, obstetrics, or public health, threatens to erode decades of public trust and will have innumerable long-term consequences for vaccine confidence, uptake, and health outcomes across the country.

Moreover, an unfavorable vote on the inclusion of maternal and pediatric RSV vaccines in the routine immunization schedule, and particularly, the failure to add pediatric RSV monoclonal antibodies to the VFC program, would have serious consequences for infant health and health equity. RSV remains a leading cause of hospitalization in infants, and both maternal immunization and pediatric monoclonal antibodies are proven tools to prevent severe disease in the earliest months of life. Excluding these interventions from the recommended schedule or the VFC program would limit access to critical protection during a child's most vulnerable period.

Lastly, the decision to include thimerosal on the agenda of the upcoming meeting of the ACIP cannot be justified based on the established science on vaccine safety and efficacy. It is an unproductive use of the committee's time and serves no discernable public health objective.

Moreover, we note that in 2020, in a bill supported by President Trump, Congress expressly directed the Secretary to award contracts or grants to "increase awareness and knowledge of the safety and effectiveness of vaccines for the prevention and control of diseases, combat misinformation about vaccines, and disseminate scientific and evidence-based vaccine-related information, with the goal of increasing rates of vaccination across all ages . . . ." 42 U.S.C. § 245. These current actions threaten this stated goal.

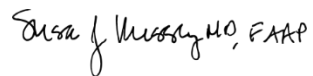
Because of these deep concerns, we respectfully urge ACIP to:

- Immediately reinstate the previous COVID-19 vaccine recommendations for children and pregnant individuals, pending a fully transparent scientific review.
- Restore the integrity of the ACIP by reinstating all seventeen prior voting members, as well as liaison representatives to the ACIP working groups.
- Commit to publishing all data and rationale underlying recent decisions that deviate from established ACIP practices and recommendations, including the data and rationale underlying the May 27 announcement regarding changes to the COVID immunization schedule.
- Preserve the current immunization schedule and ensure that any proposed changes are grounded in rigorous, evidence-based review.

- Proactively counter vaccine misinformation by avoiding messaging that legitimizes long-debunked myths and undermines public trust in immunization.

We recognize the immense responsibility borne by the CDC and ACIP in safeguarding public health. It is precisely because of this responsibility that decisions must remain rooted in science, not politics. As pediatricians committed to the health of our patients and communities, we stand ready to support efforts that reaffirm the CDC's commitment to evidence-based recommendations and the protection of all communities through immunization.

Sincerely,

A handwritten signature in black ink that reads "Susan J. Kressly MD, FAAP". The signature is written in a cursive, flowing style.

Susan J. Kressly, MD, FAAP