November 21, 2025

Advisory Committee on Immunization Practices
Centers for Disease Control and Prevention
1600 Clifton Road NE
MS H24-8
Atlanta, GA 30329-4027

Submitted electronically via regulations.gov

RE: Docket No. CDC-2025-0783, December 4-5, 2025 Meeting of the Advisory Committee on Immunization Practices

To the Advisory Committee on Immunization Practices (ACIP):

As Board Chair of the American Academy of Family Physicians (AAFP), which represents 128,300 family physicians and medical students across the country, I write to share recommendations to inform the Committee's work at the December meeting as announced in the November 13, 2025 issue of the *Federal Register*.

The AAFP believes health promotion and prevention of disease are critical and foundational components of primary care and family medicine, and vaccines remain one of our most effective tools in preventing and reducing the harms of many infectious diseases. The AAFP supports for comprehensive access to all vaccines recommended by the AAFP for individuals, regardless of socioeconomic or insurance status.

As expressed in prior communications, we remain concerned that changes to the ACIP's membership and processes are further undermining public trust in vaccines. Recent surveys indicate that public trust in the Centers for Disease Control (CDC) to provide trustworthy information has declined, with 64% of those surveyed in August 2025 stating they are confident in CDC information (down from 72% in September 2024).[i] **We urge ACIP leadership to take the following steps to bolster public trust in ACIP and CDC recommendations:**

- **Restore physician liaisons to ACIP work groups to provide input on real-world feasibility and implementation constraints of recommendations being developed;**
- **Return to the use of established procedures to develop recommendations, including the Evidence to Recommendation (EtR) framework and evaluating evidence using GRADE criteria.**

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Restore practicing physician perspectives to ACIP work group deliberations

Family physicians remain a trusted source of information about immunization to their patients,[ii] and prior to the exclusion of family physicians from ACIP working groups, they served as trusted source of information to their peers regarding the real-world implications of vaccine recommendations. We continue to be discouraged by ACIP's decision to exclude AAFP liaisons from participating in ACIP work group meetings.

When counseling patients about vaccines, family physicians consider real-world constraints such as the patient's ability to visit the office more than once as well as a parent's potential preference for a single, combination vaccine over multiple injections. Family physicians also know that different types of ACIP recommendations can impact patient access and insurance coverage. For example, when ACIP chooses to make a recommendation under "shared clinical decision-making" (SCDM), it can create additional confusion and barriers to coverage that ultimately prevent patients from accessing the vaccines they want. Some payors have interpreted ACIP SCDM recommendations as "non-routine" and declined coverage.[iii] SCDM recommendations may also create confusion and barriers that prevent patients from accessing vaccines in pharmacy settings.[iv] A recommendation for SCDM can restrict patient and parent choice about vaccines, which may run counter to ACIP's intent.

ACIP's vote to remove the recommendation for the combined MMRV vaccine removes choice for parents of children under age four who might prefer their child receive a single shot of the combined MMRV vaccine instead of separate shots of MMR and varicella vaccines. As noted during the meeting, the MMR and varicella shots are already administered separately for most children under age four, but there may be some reasons why a parent would opt for a single, combination shot after discussing the benefits and risks with their child's physician. For example, a parent of a child with a sensory disorder might feel the slightly increased risk of a febrile seizure from a combined shot is preferable to the response their child would have to two separate injections. ACIP's updated recommendation removes insurance coverage for this option, forcing a parent to pay out-of-pocket unless their insurer chooses to ignore ACIP's guidance.

It is important to remember that all ACIP recommendations are already subject to some form of individual decision-making. Physicians use immunization recommendations to counsel their patients on vaccines. Even when ACIP recommendations apply to a broad population, such as all children of a certain age, physicians may adjust their recommendation to meet the personalized needs of the individual patient before them. Moreover, patients may still choose to decline or delay immunizations even if recommended by their physician.

Many family physicians have reported that as public trust in vaccine recommendations has declined, they are spending more time than ever counseling patients about vaccines. This not only reinforces the observation that all ACIP recommendations are subject to individual decision-making, but it also suggests that family physicians and other frontline clinicians

have their finger on the pulse of how Americans weigh the benefits of vaccination with any concerns they may have. Practicing physicians could offer valuable insights to ACIP work groups, including the factors that patients consider when choosing or declining immunization. Practicing physicians can also provide information about the potential operational challenges of implementing a particular vaccine recommendation. This could include the difficulties of complex product storage and handling requirements, or the potential risks of administration errors when recommendations are complex or confusing.

We strongly recommend restoring AAFP liaisons as representatives to participate in ACIP work groups, as ACIP recommendations should be informed by real-world perspectives from those who regularly administer vaccines. During the last meeting, ACIP Chair Dr. Martin Kuldorff suggested AAFP liaisons may not participate in work groups because it is not permitted by law, specifically, the Federal Advisory Committee Act (FACA). Federal Advisory Committees may include representative members who may be selected to represent a particular point of view; these representatives are not subject to meet the same conflict-of-interest criteria as special government employee (SGE) members.[v,vi,vii] The AAFP stands ready to identify family physicians who could represent the perspective of practicing physicians and advise ACIP members on the feasibility and implementation constraints of vaccine recommendations in development.

Restore the use of the Evidence to Recommendation (EtR) framework and GRADE criteria to assess evidence

The AAFP advocates for the development and use of patient-centered, evidence-based clinical practice guidelines that adhere to principles based on the National Academy of Medicine Standards for Trustworthy Guidelines. We believe clinical practice guidelines should be informed by an independent, systematic review of the evidence and provide an adequate assessment of both benefits and harms. In 2010, ACIP adopted the use of a GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach to evaluate the quality and certainty of evidence considering factors such as study design, risk of bias, and precision. In 2019, ACIP implemented an Evidence to Recommendation (EtR) assessment that also considers risks of the public health threat, costs and benefits of intervention, feasibility of implementation, and other factors relevant to deliberation. The EtR framework has served the public well by balancing scientific rigor with clinical applicability.

We are concerned that new ACIP members (including work group members) may lack training in the GRADE or EtR frameworks. GRADE evidence tables and EtR summaries have not been prepared or shared with the public for any ACIP deliberation since April 2025. Prior to April 2025, meeting materials were published in advance, allowing ACIP members and the public to review and consider the recommendations before the committee. During recent ACIP deliberations, however, members have cited research that was, in some cases, not included in the development of the recommendation or have expressed concerns about the certainty of the research presented. Some members have resorted to presenting personal

anecdotes about vaccine safety (such as the suggestion attempting to link lung cancer to COVID-19 vaccination) or have presented lower-quality evidence during deliberations (such as a study describing the behavior of a small sample of rodents following vaccination, despite several studies presented that describe vaccine outcomes in a larger human sample). These incidents suggest that members may be uncertain about the quality of evidence considered or feel there is no established process to review the full body of evidence, which does little to bolster public trust in ACIP recommendations.

Moreover, ACIP's abandonment of the EtR process has created unnecessary confusion about the recommendation before them, including the impact of a "yes" vote, the factors and criteria used to develop the recommendation, and whether the recommendation could feasibly be implemented. For example, during the September 18th discussion on the use of the combination MMRV vaccine, voting members asked about the implementation impact of a "yes" vote to not recommend the MMRV vaccine for children under four. One member was forced to abstain because it was unclear what their vote would mean for vaccine access and insurance coverage. During discussions on the Hepatitis B vaccine, members asked for clarification about the type and timing of maternal hepatitis B testing, suggesting they lacked complete information from key stakeholder groups to understand the impact of their vote.

The confusion on display during recent meetings, in addition to the lack of transparency regarding meeting materials, is not restoring public trust in the process used to develop immunization recommendations. We therefore urge ACIP leaders to restore training and processes that incorporate GRADE assessments of the use of the EtR framework. Work group members should be trained in GRADE and EtR approaches. We also urge ACIP to make their pre-meeting deliberations more transparent by publishing EtR frameworks and materials in advance of the meeting, and once a recommendation is made, publishing the final EtR table summary with the others published on cdc.gov.

We thank you for the opportunity to share our concerns regarding changes in ACIP's process and recommendations for the voting agenda. AAFP stands ready to provide further details and support ACIP's work, if requested. Should you have any questions, please contact Julie Riley, Sr. Strategist, Regulatory and Federal Policy, at jriley@aafp.org.

Sincerely,

Jen Brull, MD, FAAFP
American Academy of Physicians, Board Chair

[i] Annenberg Public Policy Center, "Public Confidence in U.S. Health Agencies Slides, Fueled by Declines Among Democrats," September 18, 2025, https://www.annenbergpublicpolicycenter.org/public-confidence-in-u-s-health-agencies-slides-fueled-by-declines-among-democrats/
[ii] Kaiser Family Foundation, KFF Tracking Poll on Health Information and Trust: COVID-19 Vaccine Update, August 1, 2025, https://www.kff.org/health-information-trust/kff-tracking-poll-on-health-information-and-trust-covid-19-vaccine-update/
[iii] "With the Word 'May', ACIP Leaves Seniors Vulnerable To RSV This Winter", Health Affairs Forefront, July 5, 2023. https://www.healthaffairs.org/content/forefront/word-may-acip-leaves-seniors-vulnerable-rsv-winter?
[iv] Hogue MD, Foster S, Rothholz MC. Shared clinical decision making on vaccines: Nothing has really changed for pharmacists. J Am Pharm Assoc (2003). 2020 Nov-Dec;60(6):e91-e94. doi: 10.1016/j.japh.2020.06.027. Epub 2020 Jul 27. PMID: 32732103; PMCID: PMC7384787. https://pmc.ncbi.nlm.nih.gov/articles/PMC7384787/
[v] The Federal Advisory Committee Act (FACA): Overview and Considerations for Congress (2025), https://www.congress.gov/crs-product/R47984
[vi] Office of Government Ethics (OGE), Letter to the Chairman of a National Commission Dated June 24, 1993, Memorandum 93 x 14, p. 1, at https://www.oge.gov/web/oge.nsf/News+Releases/5AAC736DDAB405D4852585BA005BEE8E/$FILE/316d5bbc44074959b2638083326b850d2.pdf.
[vii] 5 U.S.C. §2105. See also GAO, Federal Advisory Committees: Additional Guidance Could Help Agencies Better Ensure Independence and Balance, April 2004, p. 18, at https://www.gao.gov/assets/gao-04-328.pdf