June 17, 2025

The Honorable Bill Cassidy, MD Chairman Committee on Health, Education, Labor and Pensions United States Senate Washington, D.C. 20510

The Honorable Mike Crapo Chairman Senate Committee on Finance Washington, D.C. 20510

The Honorable Brett Guthrie Chairman Committee on Energy and Commerce U.S. House of Representatives Washington, D.C. 20515

The Honorable Tom Cole Chairman Committee on Appropriations U.S. House of Representatives Washington, D.C. 20515

The Honorable Susan Collins Chairwoman Committee on Appropriations United States Senate Washington, D.C. 20510 The Honorable Bernie Sanders Ranking Member Committee on Health, Education, Labor and Pensions United States Senate Washington, D.C. 20510

The Honorable Ron Wyden Ranking Member Senate Committee on Finance Washington, D.C. 20510

The Honorable Frank Pallone Ranking Member Committee on Energy and Commerce U.S. House of Representatives Washington, D.C. 20515

The Honorable Rosa DeLauro Ranking Member Committee on Appropriations U.S. House of Representatives Washington, D.C. 20515

The Honorable Patty Murray Vice-Chair Committee on Appropriations United States Senate Washington, D.C. 20510

Dear Chairman Cassidy, Ranking Member Sanders, Chairman Crapo, Ranking Member Wyden, Chairman Guthrie, Ranking Member Pallone, Chairwoman Collins, Vice-Chair Murray, Chairman Cole and Ranking Member DeLauro:

On behalf of the nearly 400,000 physicians our collective organizations represent, we are deeply troubled by Department of Health and Human Services (HHS) Secretary Kennedy's unprecedented decision to remove all 17 members of the Center for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) and to ask you to use your committees' jurisdictional authority to protect our patients' access to recommended immunizations. The Secretary's action is contrary to the administration's stated goals of radical transparency and a desire to boost public trust in our vaccine systems. Instead, this dangerous decision will further erode public confidence in vaccines, undermine decades of established processes based on scientific and medical expertise, and potentially delay getting lifesaving vaccines to patients.

Vaccines are one of the safest and most cost-effective public health innovations available. Primary care physicians see firsthand how children, adults, and seniors benefit from easy, widespread access to all recommended vaccines. Since 1964, ACIP has leveraged the expertise of its members, which includes scientists, physicians, and public health stakeholders among others, to provide recommendations on vaccine administration for the U.S. population. All physicians rely on the evidence-based, thoroughly vetted decisions of expert bodies such as ACIP to help inform us and our patients about the efficacy, safety, and recommended administration of vaccines. ACIP has long been a trusted, integral piece of our nation's vaccine infrastructure, but now that is at risk.

Prior to the confirmation of Secretary Kennedy, Chairman Cassidy spoke about commitments the thennominee had made to protect the public health by maintaining existing vaccine vetting processes. Specifically, as noted in a floor speech by Chairman Cassidy:

"[Mr. Kennedy committed that], if confirmed, he will maintain the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices <u>without changes.</u>"¹

This action directly violates that commitment. Our organizations cannot stand by while core institutions and systems that protect the health of individuals, communities, and our nation as a whole are dismantled. We are calling on you as representatives of your constituents and leaders of the committees of jurisdiction to take immediate steps to investigate this decision by HHS, provide desperately-needed oversight, and proceed with legislative action, if needed, to preserve and protect ACIP's ability to carry out its mission.

Secretary Kennedy's justification for this alarming action rests on two key assertions: first, that the CDC has failed to prevent conflicts of interest from influencing ACIP recommendations, and second, that ACIP members are so deeply entrenched in the industry that they are incapable of embracing anything other than "a narrow pro-industry orthodoxy." The physicians who comprised ACIP are practicing in their communities and on the front line of patient care. This characterization is not accurate, and it creates a threat to public health when expressed by the highest-ranking health official in the federal government.

Developing vaccines is one of the most complex and resource-intensive processes in medicine. This process can take 10–15 years and cost hundreds of millions of dollars. Because of this complexity, it requires the involvement of highly trained scientists, clinicians, and public health experts with deep experience in vaccine science, epidemiology, and regulatory affairs. Vaccine trials are largely funded by vaccine manufacturers who compensate investigators leading or participating in the research. Individuals who have no prior involvement with a vaccine manufacturer are therefore unlikely to have ever witnessed the frontlines of a vaccine trial, including how data is collected and whether it is accurate or complete — key elements of "Gold Standard Science." Therefore, for ACIP to make an informed review of the data collected in vaccine trials and translate this evidence into recommendations, its members must include individuals who deeply understand the science and the system, including those who have worked in vaccine development, clinical trials, or public health implementation. ACIP

¹ Office of Senator Bill Cassidy. (2025, February 4). Cassidy delivers floor speech in support of RFK, Jr. to be HHS Secretary. U.S. Senator Bill Cassidy. <u>https://www.cassidy.senate.gov/newsroom/press-</u>releases/cassidy-delivers-floor-speech-in-support-of-rfk-ir-to-be-hhs-secretary/.

members must comply with rigorous conflict of interest requirements. The assertion that most of ACIP's members have received funding from pharmaceutical companies does not support the claim they are biased, but rather that they have the requisite experience and expertise to lead and review research critical to informing public health policy.

Today, ACIP maintains extensive policies to prevent any conflicts of interest, both for voting members as well as members of the Work Groups who develop the recommendations put forward for ACIP vote.² ACIP members, and their immediate family members, may not be employed by a vaccine manufacturer or its parent company, hold stock in such companies (in excess of the de minimus amounts defined by the Office of Government Ethics), or hold or be entitled to royalties or other compensation for a patent (planned, issued, or pending) on a vaccine that comes before ACIP during their term. They also may not participate if they are involved in research or studies of a vaccine product to be discussed or reviewed by the Work Group.

Secretary Kennedy also stated that the CDC issues "conflict-of-interest waivers to every committee member." In fact, ACIP limits the use of waivers, and when a waiver is issued, the member is only allowed to contribute to discussion and is prohibited from voting.³ This ensures that members have a deep understanding of the process and science used to assess vaccine efficacy and safety but prevents any undue influence from members over a product they are directly involved in investigating.⁴ Further, at the start of every ACIP meeting and prior to any vote, members must publicly declare any potential or even perceived conflicts of interest. This disclosure makes any perceived conflict of interest during discussion transparent. Recently, the administration developed a tool to make these statements publicly searchable, making any perceived or potential conflict of interest even more transparent.⁵

Our organizations believe the current process ACIP uses to enforce ethics rules is effective and rigorous but recognizes that ethics systems can benefit from review and modifications. We encourage Congress to work with the CDC to bolster the existing intensive and transparent ethics review process to reaffirm the advisory committee's independence. However, the current system in no way warrants total dismissal of all ACIP members. Especially as no examples or evidence have been provided that any current member of ACIP has financially benefited personally from a decision made by ACIP.

However, perhaps the most alarming assertion was suggesting that expertise itself is a form of bias. This not only discredits the rigorous processes behind vaccine policy but also discourages the very leadership and knowledge we rely on to protect populations from preventable disease.

² Centers for Disease Control and Prevention. (2022, June). Advisory Committee on Immunization Practices (ACIP) Policies and Procedures. <u>https://www.cdc.gov/acip/downloads/Policies-Procedures-508 1.pdf</u>. ³ Ibid.

⁴ Centers for Disease Control and Prevention. (2023, December). ACIP Conflicts of Interest Policy. Advisory Committee on Immunization Practices. <u>https://www.cdc.gov/acip/downloads/ACIP-conflicts-interest-policy.pdf</u>.

⁵ Centers for Disease Control and Prevention. (2025, March 7). *Conflicts of interest disclosures of ACIP members*. Advisory Committee on Immunization Practices. <u>https://www.cdc.gov/acip/disclosures/by-member.html</u>.

During consideration of Secretary Kennedy's nomination, Chairman Cassidy made a commitment regarding the oversight of the HHS Secretary, stating:

"If Mr. Kennedy is confirmed, I will use my authority as Chairman of the Senate Committee with oversight of HHS to rebuff any attempts to remove the public's access to life-saving vaccines without ironclad, causational scientific evidence that can be defended before the mainstream scientific community and before Congress. I will carefully watch for any effort to wrongfully sow public fear about vaccines between confusing references of coincidence and anecdote."

Now is the time to act upon that commitment. The spread of mis- and disinformation undermines public trust and vaccine confidence, puts populations at risk, and increases health care costs. This action will be catastrophic to public health. If an HHS Secretary is allowed to unilaterally appoint all ACIP members without utilizing a long-standing, expertly-vetted, transparent process and absent oversight from congressional leadership, the body itself can no longer be trusted.

We urge your respective committees to hold oversight hearings with Secretary Kennedy to investigate this decision and we believe that legislative action may be needed to ensure that ACIP remains a body committed to advancing evidence-based, expert-informed science and vaccine recommendations that seek to protect our nation's health.

Our organizations support House Energy and Commerce Committee Ranking Member Pallone's recently introduced legislation that would codify into law the historical process, structure and mission of ACIP. The *Family Vaccine Protection Act* (H.R. 3701) would place the current ACIP charter into statute to preserve the full scope of the committee's role.

Specifically, the bill would codify ACIP's objectives, scope of activities, advice and guidance for unlicensed vaccines, considerations for recommendation development, withdrawal of recommendations, and necessary administrative activities. In addition, the bill protects the Vaccine Injury Table (VIT) by codifying the existing VIT, including vaccines that have been added since the initial table. The bill also establishes a standard that must be met for the Secretary to remove a vaccine from the VIT. We urge you to consider this or similar legislation to support the crucial role that ACIP plays in protecting and improving public health. Further, we encourage this legislation to include sufficient guardrails that prevent any HHS Secretary from unilaterally removing any with sufficient justification to the Congress.

The public continues to rank their personal physician as the most trusted source for vaccine information.⁶ Many of our organizations have a long history of collaborating with ACIP to develop vaccine recommendations our members use to protect their patients on a daily basis, and we look forward to working with you and your colleagues in Congress to ensure that continues. We urge you to act before irreversible harm is done to the health of our nation and the systems we rely on to protect it.

⁶ Montero, A., Sparks, G., Montalvo III, J., Kirzinger, A., & Hamel, L. (2025, May 6). *KFF Tracking Poll on Health Information and Trust: Vaccine Safety and Trust.* Kaiser Family Foundation. <u>https://www.kff.org/health-information-trust/poll-finding/kff-tracking-poll-on-health-information-and-trust-vaccine-safety-and-trust/</u>.

Should you have any questions, please contact David Tully, Vice President, Government Relations, American Academy of Family Physicians at <u>dtully@aafp.org.</u>

Sincerely,

American Academy of Family Physicians American Academy of Pediatrics American College of Obstetricians and Gynecologists American College of Physicians